World Health Organization

TWELFTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS
Provisional agenda item 4

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Updates on the list of prioritized activities for the period 2022–2023

Substandard and falsified medical products and informal markets

Executive summary of literature review linked to Activity H

BACKGROUND

1. WHO has identified substandard and falsified medical products as a major health challenge: an estimated 10% of the medicines sold in low- and middle-income countries are substandard and falsified. However, substandard and falsified medical products and the types of markets through which they are distributed are yet to be comprehensively understood. In 2012, the World Health Assembly passed resolution WHA65.19, in which it decided to establish a Member State Mechanism for international collaboration among Member States from a public health perspective to address substandard and falsified medical products (at that time known as substandard/spurious/falsely-labelled/falsified/counterfeit medical products). The resolution was passed against a backdrop of increasing concern about such products and the health and socioeconomic harms they cause.

2. The workplan of the mechanism for the period 2022–2023 included Activity H to develop strategies for national regulatory authorities to mitigate public health risks posed by the distribution of substandard and falsified medical products through informal markets.[1] To this end, Working Group H commissioned a scoping review of literature on informal markets for medical products, with a focus on substandard and falsified medical products. The aim of the review was to identify and describe:

(a) the types of methodologies used to study informal markets;

(b) variations in informal markets among low-, middle- and high-income countries;

(c) data on the prevalence of substandard and falsified medical products in informal markets;

(d) the underlying causes of informal markets;

(e) data on the sources of the medical products distributed through informal markets;

[1] Document A/MSM/10/11 Rev.1, Annex 2.

(f) data on the actors involved in the distribution of medical products through informal markets;

(g) the public health and economic impacts of the medical products distributed through informal markets, with a focus on substandard and falsified medical products;

(h) types of mitigation or intervention methods and their effectiveness in controlling/limiting the distribution of medical products through informal markets, including substandard and falsified medical products; and

(i) knowledge gaps in the study of informal markets, with a focus on substandard and falsified medical products.

Scoping review methods

3. A search of the relevant literature published between 1 January 2003 and 15 May 2023 was carried out across indexing platforms, and grey literature and the references of the included studies were also screened for additional relevant literature. One search focused primarily on informal markets for medical products, and the other focused on substandard and falsified medical products. After screening and the application of inclusion criteria, a total of 241 articles were included in the literature review.

4. The full document is being finalized. Once available, it will be made available to Member States via a shared platform.

Current informal market research methodologies

5. The review identified two main approaches used to identify physical informal markets: the first approach collects information first-hand through visits to informal sellers, and the second collects information through interviews, household surveys or observations.

6. The main methodology used to identify online informal markets is content analysis through internet search engines; key phrases are used to search the internet for sellers of medical products to identify the main characteristics of illegitimate online pharmacies.

7. Researchers frequently use cross-sectional studies that incorporate a range of sampling strategies to identify informal sellers of substandard and falsified medical products in physical informal markets, including multistage, random, convenience or purposive sampling. In respect of the purchasing of medical products, a mystery-shopper approach is often applied. For studies investigating online informal markets, medical products are often bought during mapping exercises. To determine whether medical products are substandard or falsified, a range of tests is used to examine the quality of samples, including assay tests on active pharmaceutical ingredients and dissolution checks.

Variations in informal markets among low-, middle- and high-income countries

8. In the review, informal markets were categorized as either physical or online depending on their operating environment. Physical informal markets are those whereby the sale of medical products occurs in-person, regardless of whether there is a physical store, and formal vendors partaking in unregulated medical product commerce were also considered to be physical informal market actors. In comparison, online informal markets are those whereby the sale of medical products occurs via the internet.

9. In low- and middle-income countries, physical informal markets, including formal markets engaging in informal or unlicensed activities, were the main types of market identified. Informal sellers were either mobile or stationary and sold nearly all types of medicines, including antibiotics, antimalarials, antipyretics and analgesics. Formal markets engaging in informal or unlicensed activities were also common and included a range of formal sellers, including pharmacies and dispensaries. This type of informal market was characterized by non-compliance with regulations, including a lack of licences to operate, the sale of medicines beyond licence capacity, the absence of qualified or trained personnel and the sale of prescription-only medicines without a prescription. Medical products sold included antibiotics, antimalarials, rapid diagnostic tests and abortion medicines. Online informal markets were also identified in some middle-income countries and primarily included illegitimate pharmacies selling antibiotics, antihypertensives, abortion medicines and medicines for erectile dysfunction.

10. In contrast to the situation in low- and middle-income countries, the review mainly identified online informal markets in high-income countries. Most of the informal virtual sellers were illegitimate pharmacies, and a few studies also identified online and dark-web marketplaces as platforms for medical product e-commerce. In addition to the medical products found in online informal markets in middle-income countries, those in high-income countries also included vaccines, medical devices and medical supplies, such as coronavirus disease tests, ventilators, intrauterine devices and personal protective equipment.

The prevalence of substandard and falsified medical products in informal markets

11. The data gathered by the review regarding the prevalence of substandard and falsified medical products in informal markets were based on small-scale studies and were highly variable among product types and countries. Furthermore, there were no standardized methods of collecting, analysing and testing the quality of medical products, making it impossible to provide reliable representative prevalence estimates.

Drivers of informal markets

12. Common drivers of the distribution of substandard and falsified medical products through informal markets in low- and middle-income countries were comparable and included: unavailability in and/or the high prices of the formal sector; geographical accessibility; long waiting times in the formal sector; the flexible opening hours of informal markets; trust in and familiarity with informal providers; perceptions of better-quality services as provided by informal markets; a lack of personnel in the formal sector; perceived unprofessional or negative attitudes of formal-sector providers; financial incentives for informal providers; the desire of informal providers to help communities; weak or non-existent regulatory oversight, legal systems and drug regulatory bodies; and a lack of knowledge among consumers about quality of or access to care.

13. In high-income countries, the main drivers of the distribution of substandard and falsified medical products through informal markets included: unavailability in and/or the high prices of the formal sector; the perceived privacy of buying online; the convenience of buying online; a lack of or limited health insurance; affliction with a chronic condition; exposure to direct-to-consumer advertising; and an inability among consumers to differentiate between legitimate and illegitimate online pharmacies.

Informal market stakeholders and medical product sources

14. The review identified four main types of stakeholder in low- and middle-income countries in respect of the distribution of substandard and falsified medical products through physical informal markets: buyers, sellers and suppliers of medical products, and national and regional regulatory authorities. Pharmaceutical sales representatives, who in some countries promote their products among informal sellers, were identified as a distinct group in middle-income countries. Identified buyers of medical products included parents and/or caregivers of children, self-medicating community members and women seeking chemical abortions. Identified informal sellers included unqualified or untrained personnel at registered pharmacies and unlicensed sellers. Identified informal suppliers were individuals or entities supplying medicines to informal resellers, and identified informal sources included: local retailers; wholesalers; health care providers; individuals selling residual medical products; licensed pharmacies and private dispensaries; pharmaceutical companies and representatives; procurement agencies; and diversions from the legitimate supply chain. Some studies found that national and regional regulators, which are responsible for ensuring that medical products meet quality, safety and efficacy standards while safeguarding supply chains, were aware of the distribution of medical products through informal markets but allowed such commerce to continue because they acknowledged the communities' health needs.

15. The review identified two main types of stakeholder in middle- and high-income countries in respect of the distribution of substandard and falsified medical products through online informal markets: buyers and suppliers of medical products. Identified buyers of medical products included women seeking abortions, people with chronic conditions and people who wanted to buy medical products anonymously. Identified informal sources of medical products included shipments from other countries, smuggled goods and thefts and diversions from manufacturers, distributors and health care providers.

Health and economic impacts

16. Informal markets for medical products can negatively impact health in a myriad of ways; they have, for example, driven inappropriate self-diagnosis and self-prescription, which can lead, inter alia, to medically unnecessary behaviour, overprescription and drug-to-drug interactions. Furthermore, the quality of medical products bought from informal markets cannot be guaranteed owing to the prevalence of substandard and falsified medical products. Consequently, there is a risk of death, and multiple studies have also raised the issue of the increased risk of antimicrobial resistance.

17. The few studies that have reported on the economic impacts of the distribution of substandard and falsified medical products through informal markets have notably identified an increased financial burden on consumers owing to prolonged illness from ineffective, insufficient dosage or substandard medical products and the subsequent need to purchase additional medical products.

Intervention strategies

18. To regulate physical informal markets in low- and middle-income countries, regulatory authorities assess and control the required qualifications, training, licensing and registration status of sellers of medical products, and the types of medical products sold. Approaches that have been adopted to reduce the potentially harmful impacts of the distribution of substandard and falsified medical products through informal markets include the cessation of the activities of informal market vendors and the confiscation of goods. National regulatory authorities have also trialled interventions that maintain medical product commerce in a safer, official capacity by integrating informal market sellers into the formal sector through training and accreditation requirements. However, no evidence has been identified to determine the long-term effectiveness of these strategies.

19. The review did not gather sufficient evidence to determine either the nature or the extent of regulatory responses to online informal pharmacies among low- and middle-income countries. In high-income countries, the strategies employed by national regulatory authorities to combat online informal markets include: requiring the accreditation of and monitoring online pharmacies; the provision of operational guidelines; the issuance of warning letters; national coordination among different government ministries; and collaboration among Member States to identify and close illegitimate online pharmacies and intercept shipments of substandard and falsified medical products. Other strategies that have been adopted in high-income countries include consumer education and advocacy to increase awareness in respect of the risks of buying medical products from illegitimate online pharmacies.

20. With regard to global initiatives to limit the distribution of substandard and falsified medical products through informal markets, the review identified legislative action by international bodies (for example, the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, the European Union Falsified Medicines Directive and the Lomé Initiative). However, these international instruments do not specifically target informal markets; instead, they aim to remove substandard and falsified medical products from circulation, irrespective of their source. Initiatives to regulate medical product supply chains include the use of unique medical product identification codes to determine authenticity. Pharmacovigilance and the reporting of substandard and falsified medical products (for example, by Member States to the WHO Global Surveillance and Monitoring System for substandard and falsified medical products) were also identified as intervention strategies to help detect and respond to known risks in respect of substandard and falsified medical products.

Research and knowledge gaps

21. The review identified a disparate set of studies that had attempted to document the status of the distribution of substandard and falsified medical products through informal markets in low-, middle- and high-income countries. However, categorical research and knowledge gaps persist, for which reason there is a lack of or limited up-to-date, actionable evidence on:

(a) country-level information as regards the structure and function of informal markets, including drivers and stakeholders;

(b) the availability and affordability of medical products distributed through informal markets relative to those distributed through formal markets;

(c) the prevalence of substandard and falsified medical products in informal markets, including cost-effective methods used to assess the quality of medical products;

(d) the sources and supply chains of medical products distributed through informal markets;

(e) the health and economic impacts of the distribution of substandard and falsified medical products through informal markets; and

(f) holistic mitigation and intervention strategies to regulate informal markets and limit the distribution of substandard and falsified medical products through these channels.

ACTION BY THE MEMBER STATE MECHANISM

22. The mechanism is invited to note the executive summary. In its discussions, it is further invited to reflect on the main outcomes of the review presented here and provide comments and guidance in respect of the following questions.

- With respect to the distribution of substandard and falsified medical products through informal markets, what aspects should be considered to develop a standardized methodology that is adaptable to low-, middle- and high-income countries, empowering Member States to study physical and online informal markets systematically in their respective jurisdictions?

- Do Member States have additional literature sources (including grey literature) to supplement the findings of the review?

- In the next phase of the activities of Working Group H it is proposed to include the collection of data from Member States directly in order to understand better their respective informal markets. Are there any specific considerations that should be taken into account in this regard by Working Group H?

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