

The link between constrained access to quality, safe, efficacious and affordable medical products and substandard and falsified medical products

Report by the Secretariat on Activity D

BACKGROUND

1. At its eighth meeting, the Member State mechanism on substandard and falsified medical products agreed a list of prioritized activities for the period 2020–2021.¹ Activity D of that list aims to increase Member States’ knowledge around the links between substandard and falsified medical products and access to quality, safe, efficacious and affordable medical products. The Secretariat leads this activity.
2. At the eighth meeting of the Member State mechanism, the Secretariat presented data from the WHO Global Surveillance and Monitoring System for substandard and falsified medical products, disaggregated by access criteria. At present, the Global Surveillance and Monitoring System gathers reports from national regulatory focal points, but in the future it is expected that this database will be connected to other internal and external data sets (e.g. the Global Benchmarking Tool, model lists of essential medicines and health products, pharmacovigilance, etc.).
3. At the June 2020 meeting of the Steering Committee, the Secretariat presented draft recommendations that advocated for improved governance of supply chains and regulation in order to prevent, detect and respond to substandard and falsified medical products, pursuant to the WHO road map for access to medicines, vaccines and other health products, 2019–2023² and per the scope of the Member State mechanism.
4. This report explains the rationale behind the proposed recommendations and sets out tangible steps for implementation, taking into account the impact of the ongoing coronavirus disease (COVID-19) pandemic.

PROBLEM STATEMENT

5. The “triple billion” objectives of the WHO Thirteenth General Programme of Work, 2019–2023 cannot be achieved without ensuring that the world’s populations have access to safe, efficacious,

¹ Document A/MSM/8/4.

² Available at https://www.who.int/medicines/access_use/road-map-medicines-vaccines/en/ (accessed 5 October 2020).

affordable and quality medical products. Substandard and falsified medical products are a longstanding threat that undermine all public health investments.

6. Substandard and falsified medical products are more likely to reach patients under certain conditions, including situations involving constrained access, weak regulatory capacity and poor governance.¹ Supply–demand shifts (from ingredients to finished products), new distribution channels, fluid regulatory environments and overburdened regulators exacerbate the constraints on access.

7. The current COVID-19 crisis poses even greater challenges in developing, regulating and distributing diagnostics, therapeutics and vaccines to populations with diverse health conditions. From January to August 2020, over 300 published articles documented substandard and falsified health products related to COVID-19² circulating and being advertised and sold through multiple channels across the world, including via social media platforms.³ Since January 2020, the WHO Global Surveillance and Monitoring System has issued multiple global alerts⁴ and notices reflecting increased reports of both substandard and falsified medical products related to COVID-19.

8. It is essential to understand how substandard and falsified medical products weaken progress towards access to quality, safe, efficacious and affordable medical products in order to develop appropriate mitigation strategies.

Regulatory authorities play an essential role in shaping and executing policies that ensure access to quality, safe, effective and affordable medical products. Their expertise is particularly vital during the current pandemic where the adoption and implementation of appropriate policies will greatly impact access to medicines, both now and in the post-COVID-19 future.

LEVERAGING EXISTING FRAMEWORKS

WHO road map for access to medicines, vaccines and other health products

9. The 2019 United Nations political declaration of the high-level meeting on universal health coverage provides for access to safe, quality, efficacious and affordable medical products without financial hardship for all people.⁵ Despite some progress, at least half of the world's population still cannot obtain essential health services. In 2019, the Seventy-second World Health Assembly noted the draft road map for access to medicines, vaccines and other health products, 2019–2023, which links

¹ WHO Global Surveillance and Monitoring System for substandard and falsified medical products. Geneva: World Health Organization; 2017. (<https://www.who.int/medicines/regulation/ssffc/publications/gsms-report-sf/en/>, accessed 5 October 2020).

² Van Assche K, Caillet C, Newton P. Medical Product Quality Report – COVID-19 Issues. 2020 (https://www.iddo.org/sites/default/files/publication/2020-08/Medical%20Product%20Quality%20Report_Covid-19%20Issues_Issue%201%20Jan-June%202020_Main%20text_12aug2020.pdf, accessed 5 October 2020).

³ Mackey TK, Li J, Purushothaman V, Nali M, Shah N, Bardier C, et al. Big Data, Natural Language Processing, and Deep Learning to Detect and Characterize Illicit COVID-19 Product Sales: Infoveillance Study on Twitter and Instagram; JMIR Public Health Surveillance. 2020;6(3):e20794.

⁴ Available at <https://www.who.int/medicines/publications/drugalerts/en/> (accessed 5 October 2020).

⁵ Available at <https://undocs.org/en/A/RES/74/2> (accessed 5 October 2020).

equitable access to safe, efficacious, quality and affordable products to target 3.8 of the Sustainable Development Goals.¹

10. The first strategic area of the road map focuses on ensuring the quality, safety and efficacy of health products through regulatory system strengthening, pre-qualification, and post-market surveillance of products overseen by national regulatory authorities. Regulatory system strengthening underpins all aspects of supply chain integrity. The second strategic area aims to improve equitable access through research and development that meets public health needs and improves access to health products; evidence-based selection and fair and affordable pricing; procurement and supply chain management; and appropriate prescribing, dispensing and rational use. Both these strategic areas shape availability, affordability and acceptability, and prevent substandard and falsified medical products from entering the market and reaching patients.

The Member State mechanism on substandard and falsified medical products and the prevent-detect-respond framework

11. Resolution WHA65.19 (2012) recognizes that substandard and falsified medical products are an unacceptable threat to public health. The resolution also provides for the establishment of the Member State mechanism whose goals are to: (i) protect public health and promote access to affordable, safe, efficacious, and quality medical products and (ii) promote the prevention and control of substandard and falsified medical products and associated activities.

12. In 2017, the Member State mechanism developed a framework of action to prevent, detect and respond to substandard and falsified medical products. The framework provides guidance to national health authorities on regulatory system strengthening, supply chain integrity and multistakeholder engagement.² Managing the risks of substandard and falsified medicines can be done: (i) through the well-regulated supply and delivery of medical products and (ii) by minimizing the drivers of poor access, including lack of availability and affordability. Ensuring equitable and quality access while preventing substandard and falsified medical products require systems that are stable, well-established and integrated within and across both strategic areas of the road map for access to medicines, vaccines and other health products.

EVIDENCE THAT SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS OBSTRUCT ACCESS TO QUALITY, SAFE, EFFICACIOUS AND AFFORDABLE MEDICAL PRODUCTS AND RELATED PUBLIC INVESTMENTS

13. Literature reviews and thematic analysis of the reports submitted to the WHO Global Surveillance and Monitoring System have revealed four main links between access to quality, safe, efficacious and affordable medical products and substandard and falsified medical products. Each of these links falls within the strategic areas of the road map for access to medicines, vaccines and other health products.

¹ Resolution WHA72.8 (2019) and document A72/17.

² Document A70/23.

Links between universal health coverage, regulatory capacity and substandard and falsified medical products (accessibility)

14. Inadequate coverage of essential services by health insurance schemes and weak regulatory capacity are associated with substandard and falsified medical products.¹ These issues are caused by gaps in (i) pricing and supply chain governance and (ii) regulation, two strategic areas targeted by the road map. Over two thirds of the substandard and falsified medical product reports submitted to the Global Surveillance and Monitoring System are from countries where the universal health coverage service coverage index is inferior to 60.

Links between price, affordability and substandard and falsified medical products (affordability)

15. According to the road map, a fair price is one that is affordable for health systems and patients and at the same time provides sufficient market incentive for industry to invest in innovation and the production of medicines.² The price of a medical product must be considered within local economic context and in relationship to high demand/limited availability (including epidemiological burden). Over half of the substandard and falsified medical product reports submitted to the Global Surveillance and Monitoring System relate to medical products included on model lists that cost less than US\$10 per pack. Most of these reports come from low- and middle-income countries.

Links between shortages, weak procurement and substandard and falsified medical products (availability)

16. Supply chain integrity is compromised by incidents of substandard and falsified medical products when there are shortages and weak procurement management. This affects public sector and subsidized supply chains most when there is also weak regulatory capacity. Supply chain risks are exacerbated in remote areas with limited alternatives, settings with complex payment mechanisms, and for products with insufficient forecasting. Two thirds of substandard and falsified medical products reported to the Global Surveillance and Monitoring System from low- and middle-income countries are discovered at patient level and are associated with limited availability.

Links between prescribing, dispensing, rational use, and substandard and falsified medical products (acceptability)

17. Prescribing, dispensing and rational use should be guided by regulatory requirements to ensure safety, quality and efficacy. Labelling, prescribing and dispensing serve as a last line of defence against the risk of substandard and falsified medical products. Substandard and falsified versions of essential medical products with flawed packaging and/or visible inferior quality (i.e. low acceptability criteria) are most often reported to the Global Surveillance and Monitoring System from locations with limited availability.

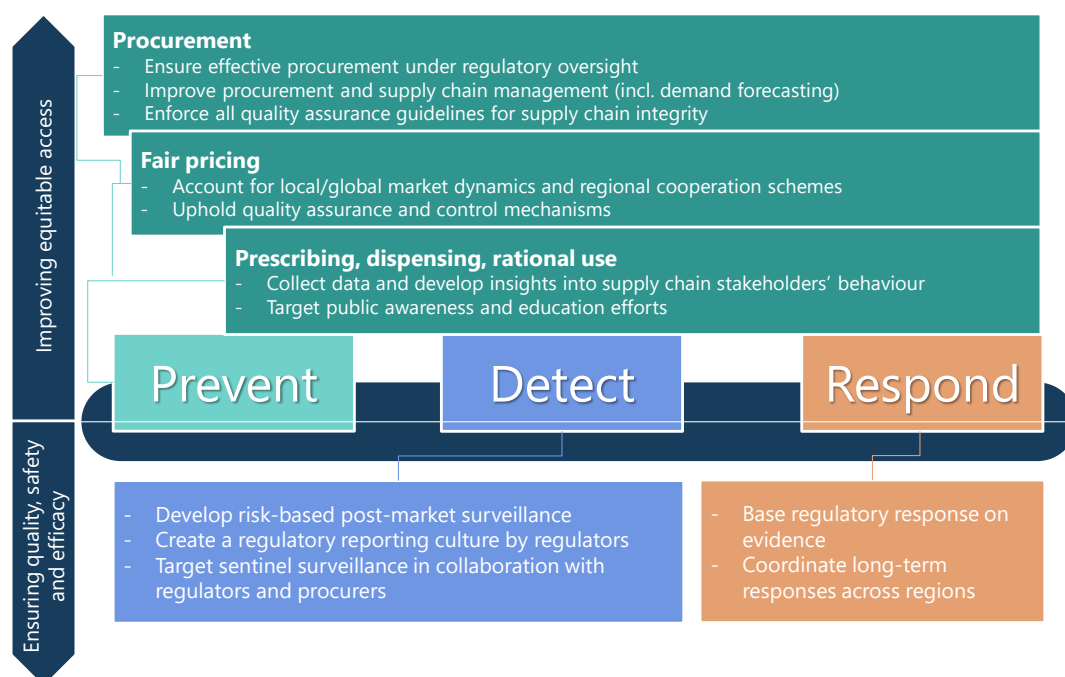
¹ Ozawa S, Pribluda VS, Yemeke T, Higgins C, Hajjou M, Evans III L, et al. Integrating Medicines Quality Assurance into Universal Health Coverage Programming: A path to reducing waste and increasing access to essential medical products. Promoting the Quality of Medicines. 2019. (<https://www.usp-pqm.org/sites/default/files/field/image/pqm-uhc-white-paper.pdf>, accessed 5 October 2020).

² Document A72/17.

MAPPING THE PREVENT-DETECT-RESPOND FRAMEWORK TO THE ROAD MAP FOR ACCESS TO MEDICINES, VACCINES AND OTHER HEALTH PRODUCTS

18. Fig. 1 illustrates how prevention functions predominantly, but not exclusively, fall under the equitable access strategic area of the road map (improved governance) and detection and response functions fall under quality, safety and efficacy (improved regulation).

Fig. 1. Mapping the prevent-detect-respond framework to the road map for access to medicines, vaccines and other health products



PROPOSED RECOMMENDATIONS FOR THE MEMBER STATE MECHANISM

19. The mandate for universal health coverage and the globalized supply of medical products place high demands and pressure on regulators. Already insufficiently staffed regulatory authorities face increasing workloads and are challenged by regulating more complex products and novel pandemic medical countermeasures. While implementing good regulatory and reliance practices can help to execute some core regulatory functions, it is also important to leverage the competencies of policy-makers, procurers, distributors, practitioners, patients and consumers in order to reduce the burden of substandard and falsified health products on the market and their harm to patients and public health.

20. Findings suggest that the best approach to health system investment is one that bolsters regulatory capacity, particularly in post-market surveillance and supply chain integrity, and enhances multistakeholder collaboration to prevent drivers of substandard and falsified medicines in the market. Good regulatory governance is key to this approach. Efforts should therefore be made to:

- Strengthen collaboration across both strategic areas of the road map for access to medicines, vaccines and other health products – specifically prevention and detection efforts, including in

price determination – to uphold safety, quality and efficacy; monitor shortages and supply disruptions; reduce cost-cutting that compromises supply chain integrity; and better target risk communication. The Member State mechanism may wish to support this cross-cutting approach.

- Address gaps in data and reporting to generate broader evidence of the links between substandard and falsified medical products and various access constraints, in particular by:

- (i) Continuing and expanding reporting to the relevant national authorities and WHO.

Data of quality in appropriate quantities is required to develop evidence-based policies and procedures. This can only happen if supported by national leadership. High levels of reporting must be positively interpreted as a measure of effective regulatory oversight and capacity and not extrapolated to national prevalence levels. The Member State mechanism may wish to support this paradigm shift.

- (ii) Ensuring connections are established between relevant databases in order to strengthen evidence and improve planning and response.

It is important to pool data from disparate systems. Any parallel reporting system that maps access criteria and substandard and falsified medical products should be connected to the WHO Global Surveillance and Monitoring System. National reporting systems should include the Global Surveillance and Monitoring System as part of their process, where appropriate. The Member State mechanism may wish to support the development of such connections.

ACTION BY THE MEMBER STATE MECHANISM

21. The Member State mechanism is invited to note this report.

22. The Member State mechanism is further invited to consider the recommendations contained in paragraphs 19 and 20 and agree on a way of moving forward.

= = =