

10. Substandard and falsified medical products

Statement:

We welcome the report on substandard and falsified medical products (SFMP) as well as the one on the standardization of medical device nomenclature. Actions to address the drivers of SFMPs need to address the root causes that enable the circulation of quality-compromised medicine, such as the lack of equitable access to medicines, high drug pricing, supply and demand issues, and regulatory failures.

Access to UHC combined with a robust public health system and affordable pricing can eliminate the circulation of SFMPs. IP protections such as patents adversely impact drug pricing and access to affordable medicines. The removal of these barriers enables local production to meet medicine shortages. Regulatory strengthening should focus on the facilitation of access to quality medicines and rather than create additional barriers to access in disguise of quality.

The current WHO collection does not differentiate between substandard and falsified products. This differentiation would enable evidence-based resource allocation to better address the specific issue of each. A single nomenclature system is crucial from a public health perspective and requires strong regulations.

WHO must maintain control of the standardization and regulation of medical devices. This should not be driven by the medical device industry that is interested in maintaining its market monopoly and profit rather than addressing public health needs. An essential medical devices list is important. COVID-19 exposes the burden and shortfall of the lack of medical devices and its impact on patient health, quality of care and health-workers safety.

Manufacturing needs to be scaled-up and strengthened, especially in low and middle income countries. This requires technology transfer and addressing trade and supply barriers. The nomenclature system can positively influence local production of medical devices and ensure accessibility and affordability.