
WHO Global Surveillance and Monitoring System for Substandard and Falsified (SF) Medical Products¹

Terms of Reference

1. To significantly improve the quantity, quality and analysis of data on SF medical products through collaboration with Member States in an inclusive effort to protect public health.
2. To establish and maintain a sustainable global surveillance and monitoring system for the collection, dissemination and analysis of validated data on SF medical products.
3. To create a system encouraging the concise, systematic and structured reporting of SF medical products between Member States and WHO.
4. To securely store reports of SF medical products incidents in accordance with established WHO IT² security criteria.
5. To accurately assess the scope, scale and socio-economic harm³ caused by SF medical products.
6. To use the collected and validated data to identify medical products and populations most at risk, vulnerabilities in supply chains, and weaknesses in health systems.
7. To use the collected and validated data to assist Member States in the development of policy and procedures and inform investment and capacity building in relation to the prevention, detection and response to SF medical products.
8. To issue Medical Product Alerts in accordance with established WHO criteria⁴.
9. To create a global network of focal points⁵ within National and Regional Regulatory Authorities, trained in the use of the global surveillance and monitoring system on SF medical products.
10. To provide designated and trained focal points, within National and Regional Regulatory Authorities, with functional access to the global surveillance and monitoring database.
11. To provide or facilitate timely technical assistance to Member States, when requested, to protect public health.
12. To contribute to the work of the Member State Mechanism on SF Medical Products.
13. To operate the WHO Global surveillance and monitoring system in a transparent and inclusive manner with Member States.

¹ A/SSFFC/WG/5 Medical products includes Medicines, Vaccines and In-Vitro diagnostics

² WHO Global Information Security Program 2013

³ Excluding IPR considerations

⁴ <http://www.who.int/medicines/regulation/ssffc/medical-products/en/>

⁵ <http://www.who.int/medicines/regulation/ssffc/mechanism/terms-of-ref-focal-point-network.pdf?ua=1>