

Updates on the prioritized activities for 2024–2025, including the strategic plan

Revised terms of reference for the Global Focal Point Network for substandard and falsified medical products

Report by the Director-General

Background

1. The circulation of substandard and falsified medical products represents a serious threat to public health, undermining patient safety, treatment outcomes and trust in health systems. In 2012, the Sixty-fifth World Health Assembly adopted resolution WHA65.19 in which it decided to establish the Member State mechanism to address the global challenge of substandard and falsified medical products through the fostering of intergovernmental collaboration and access to affordable, safe, efficacious and quality medicines.
2. To enhance global coordination, WHO established the Global Focal Point Network for substandard and falsified medical products following an agreement by the Member State mechanism at its third meeting in October 2014.¹
3. Since its establishment,² the Network has strengthened information exchange and collaboration among Member States. The Network has expanded significantly over the years and currently encompasses over 180 Member States with national focal points nominated by national regulatory authorities and/or ministries of health. The Network serves as a key platform for real-time communication, enabling national regulatory authorities and WHO to share intelligence, issue public health risk alerts and coordinate responses to substandard and falsified medical products.
4. The evolution of the WHO Global Surveillance and Monitoring System has further strengthened the role of national focal points by providing a structured and secure platform for reporting and analysing incidents involving substandard and falsified medical products.

¹ See document A/MSM/3/3 Annex 3.

² See document A/MSM/4/2.

5. The present document contains the revised terms of reference for the Network. The revised terms of reference reflect the developments within and progress made by the Network and emphasize the enhanced role and responsibilities for designated national focal points, including key performance expectations in respect of risk communication, data sharing and collaboration. They acknowledge the critical contributions of national focal points in regulatory decision-making and public health protection and reinforce national focal point responsibilities in ensuring timely and accurate reporting of substandard and falsified medical products. The revised terms of reference also incorporate lessons learned and best practices to further strengthen global coordination efforts.

Purpose and objectives of the Global Focal Point Network for substandard and falsified medical products

6. The main purpose of the Network is to facilitate effective communication and collaboration between the WHO Secretariat and Member States to combat substandard and falsified medical products in line with the global strategy to prevent, detect and respond to substandard and falsified products.

7. The objectives of the Network are to:

- (a) report incidents and communicate information on substandard and falsified medical products to WHO through the Global Surveillance and Monitoring System;
- (b) strengthen capacity in early detection and investigation of substandard and falsified medical products and facilitate dialogue among national regulatory authorities, Member States and the WHO Secretariat to develop a robust and comprehensive approach to mitigate the circulation of substandard and falsified medical products;
- (c) develop a successful network that is designed around sharing experiences, good practices and technical knowledge among Member States at the regional and global levels to promote replication of best practices; and
- (d) contribute to WHO processes by providing feedback on technical documents, guidance and workstreams and facilitate the implementation of relevant WHO tools, resources, workplans and initiatives at the national, regional, and global levels.

Glossary

8. **National focal point:** An officially designated individual who acts as a single point of contact for reporting substandard and falsified medical products to the Global Surveillance and Monitoring System and who is responsible for responding on behalf of the relevant national regulatory authority and/or ministry of health during data collection and consultation processes. The national focal point should hold appropriate qualifications, have access to relevant information, be integrated into national and regional alert structures and receive support from senior management to share information in a timely manner.

9. **Global Focal Point Network for substandard and falsified medical products:** A WHO-managed network of designated national officials established to facilitate the timely and accurate exchange of information related to substandard and falsified medical products.

10. **WHO Global Surveillance and Monitoring System:** A WHO-led system established in 2010 to combat substandard and falsified medical products. The System is responsible for collecting data on and addressing the scope and impact of substandard and falsified medical products and for providing Member States with the relevant guidance, technical assistance and capacity building to address those products. It functions through a global network of national focal points and partners responsible for strengthening regulatory systems and promoting international coordination to safeguard the quality and safety of medical products.

11. **Designated institution:** An officially appointed organization responsible for hosting and supporting the national focal point and for facilitating coordination, communication and implementation of related activities for the Network. The institution plays a critical role in the functionality and effectiveness of the national focal point network, ensuring a robust and reliable framework for communication and action.

Roles and responsibilities

WHO Secretariat

12. The WHO Secretariat is responsible for supporting the Network in undertaking the following activities.

- (a) Develop guidance documents, handbooks and training norms and standards to support Member States in combating substandard and falsified medical products.
- (b) Develop road maps for technical staff on substandard and falsified product investigation and sustainable action implementation to combat substandard and falsified medical products.
- (c) Provide technical guidance on risk-based market surveillance and control tools.
- (d) Conduct training needs assessments and design customized training plans.
- (e) Deliver training and maintain curricular oversight.
- (f) Provide access to online training tools and administer the Global Surveillance and Monitoring System platform.
- (g) Maintain and update the national focal point directory and ensure secure data handling.
- (h) Coordinate and facilitate communication within the Network.
- (i) Convene, where appropriate, global and regional meetings, technical webinars and ad hoc consultations (held in person, online or in a hybrid format).
- (j) Ensure that all substandard and falsified reports submitted by national regulatory authorities or ministries of health are shared with the Network as well as the designated regional networks to ensure coordinated action, avoid duplication of reporting and facilitate secure and interoperable data exchange.
- (k) Collect, analyse and publish data trends through regular Global Surveillance and Monitoring System reports.

- (l) Disseminate WHO medical product alerts and risk communication materials.
- (m) Promote and support multilateral and inter-agency collaboration, including regulatory networks, enforcement authorities and other WHO workstreams.
- (n) Monitor implementation and impact of WHO-supported substandard and falsified initiatives.
- (o) Ensure secure, confidential and appropriate handling of sensitive information and data.
- (p) Maintain and update the Network's online presence and curate accessible resources.

Member States

13. Member States have the following roles and responsibilities.

- (a) Identify and nominate appropriate individuals and/or designated institution/offices to receive, communicate and respond to enquiries related to substandard and falsified medical products based on their regulatory and administrative structures (the national focal points should be officially nominated by the relevant national authority).
- (b) Nominate at least one, and no more than three, staff members within the national regulatory authority or ministry of health to serve as national focal points for substandard and falsified medical products and notify the WHO Secretariat via official courier or email of the corresponding contact details and addresses, specifying both the personnel and the institution they represent so as to ensure continuity and accountability.
- (c) Communicate the following contact details to the WHO Secretariat:
 - name of the designated institution
 - address of the designated institution
 - name and administrative title of the head of or responsible individual within the designated office
 - names of nominated national focal points within the designated institution/office, including the primary and no more than two alternate national focal points
 - generic and individual email addresses for the office and individual national focal points
 - telephone numbers.
- (d) Notify the WHO Secretariat of any changes to the designated institution or responsible national focal points. The contact details of the designated national focal point shall be annually confirmed with the WHO Secretariat.

- (e) Provide the national focal points with the authority and resources needed to carry out their functions, including the authority to report to the Global Surveillance and Monitoring System, access and share information, convene meetings and coordinate with other agencies.
- (f) Provide the national focal points with the authority and capacity to receive and respond to medical product alerts at the national, regional and global levels.

Designated institutions

14. The designated institutions have the following roles and responsibilities.

- (a) Be the official entity through which the Member State communicates with the WHO Secretariat and other Member States regarding substandard and falsified medical products.
- (b) Ensure that national focal points are readily contactable by providing functional and reliable communication systems, including telephone, email and, where appropriate, videoconference facilities (primary means of contact should include both a generic institutional email and direct contact details for the named national focal points).
- (c) Provide national focal points with the authority and resources needed to carry out their functions, including the authority to report to the Global Surveillance and Monitoring System, access and share information, convene meetings and coordinate with other agencies.

National focal points

15. The national focal points have the following roles and responsibilities.

- (a) Represent the national regulatory authority and/or ministry of health in an official capacity and serve as the primary liaison with the WHO Secretariat on substandard and falsified medical products matters under the guidance of the designated institution.
- (b) Coordinate national responses to WHO alerts and substandard and falsified incidents, report to the Global Surveillance and Monitoring System and support implementation of WHO tools and strategies.
- (c) Consent to share contact details within the Network, remain easily contactable and respect confidentiality protocols, especially for sensitive data and investigations.
- (d) Complete mandatory training on substandard and falsified medical products and on Global Surveillance and Monitoring System platform usage, and subsequently use the secure Global Surveillance and Monitoring System platform for communication and reporting.
- (e) Work closely with national government entities (for example, quality control laboratories, pharmacovigilance centres, poisons centres, healthcare providers), law enforcement agencies, the criminal justice system and stakeholders involved in the licensed manufacture, distribution and supply of medical products to ensure that suspected substandard and falsified medical products are addressed in a timely, coordinated and proportionate manner.

- (f) Ensure timely reporting of suspected or confirmed substandard and falsified incidents via the Global Surveillance and Monitoring System and other standard reporting systems and share national data, policy updates and investigation outcomes with the WHO Secretariat.
- (g) Contribute to WHO efforts to develop, review and update norms and standards, strategies and tools by providing national feedback, and disseminate and support implementation of WHO guidance at the national level.
- (h) Engage in WHO-organized meetings, trainings and workshops and promote knowledge sharing within institutions and across the Network.
- (i) Support public awareness and community engagement efforts related to substandard and falsified medical products.
- (j) Report on progress, challenges and best practices related to national actions on substandard and falsified medical products to inform global learning and strategic planning.

Key performance indicators

16. The Network may identify and agree upon a set of key performance indicators to monitor its effectiveness and impact. These key performance indicators could cover areas such as the timeliness of reporting suspected substandard and falsified medical products, the quality and completeness of information shared, the responsiveness to WHO requests and the extent of collaboration with relevant national stakeholders. Once agreed, the key performance indicators should be shared on the Global Surveillance and Monitoring System platform to provide common guidance for national focal points and to facilitate consistent measurement, benchmarking and continuous improvement across the Network.

Ethical considerations and conflicts of interest

17. All individuals operating under these terms of reference must uphold the highest ethical standards, including confidentiality, integrity and transparency.

18. The WHO Secretariat shall ensure that training and other activities provided to the Network are free from conflicts of interest. National focal points must disclose any real or perceived conflicts of interest.

19. The information recorded in the Global Surveillance and Monitoring System database, whether or not reported by national regulatory authorities and/or ministries of health, may be used by WHO in the best interests of public health. The WHO Secretariat may publish parts of this information in the form of risk communication (such as WHO Medical Product Alerts) or in the context of academic research, subject to WHO's broader policies on data, research and publications.

Duration of assignment

20. The duration of national focal point appointment shall be continuing until such time as new nominations are received or the present incumbents step down.

Review of the terms of reference

21. These terms of reference shall be reviewed and updated as necessary based on evolving needs and WHO priorities.

Action by the Member State mechanism

22. The mechanism is invited to note this report and approve the revised terms of reference.
