

## **Draft list of prioritized activities to implement the workplan of the Member State mechanism for the period 2026–2027**

**Updated following the Steering Committee meeting in July 2025**

### **Background**

1. In May 2014, the Sixty-seventh World Health Assembly noted the workplan of the Member State mechanism on substandard and falsified medical products as published in Appendix 2 to document A67/29.<sup>1</sup> Since 2014, the mechanism has agreed on a biennial list of prioritized activities to implement the workplan. The current list of prioritized activities covers the period 2024–2025.<sup>2</sup> The draft list of prioritized activities for the period 2026–2027 will be considered at the fourteenth meeting of the mechanism in November 2025 (see Annex 1).

2. At its July 2025 meeting, the Steering Committee recommended reducing the overall number of prioritized activities in the light of WHO's financial and restructuring constraints. These recommendations were further discussed and agreed upon with the Working Group Chairs on 1 October 2025.

### **Current status**

3. For the period 2026–2027, the following changes are proposed to the draft list of prioritized activities:

- (a) reduction of 10 to three prioritized activities;
- (b) merging of prioritized activities A, C and E for the period 2024–2025 into one new prioritized Activity A, with revised text;
- (c) merging of prioritized Activities G and H for the period 2024–2025 into one new prioritized Activity B;
- (d) maintaining of prioritized Activity F as a standalone activity and renaming it as the new prioritized Activity C;

---

<sup>1</sup> See document WHA67/2014/REC/3, summary record of Committee B, fourth meeting, section 2.

<sup>2</sup> Document A/MSM/12/10, Annex 1.

- (e) changes made by the technical team, as recommended by the Steering Committee, to the wording of the new prioritized Activities A and B, including to the “Name”, “Proposed actions”, “Metrics/Success indicators” and “Expected outcomes” columns;
- (f) changes to the wording of the prioritized activities “Name”, “Proposed actions”, “Metrics/Success indicators” and “Expected outcomes” column, made in coordination with the respective working group chairs; and
- (g) requirement for all working groups to have dedicated chairs, co-chairs and subgroups, as appropriate, to complete the actions under the prioritized activities.

### **Action by the Member State mechanism**

4. The mechanism is invited to note the report and approve the draft list of prioritized activities to implement the workplan of the Member State mechanism for the period 2026–2027, together with the strategic plan (see Annex 2).

## Annex 1

### Draft list of prioritized activities to implement the workplan of the Member State mechanism for the period 2026–2027

| Prioritized activities                                                                                                                                                                  | Proposed actions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Metrics/Success indicators                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Expected outcomes                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>A. Strengthen regulatory capacity, detection technologies, and risk communication to prevent, detect, and respond to substandard and falsified medical products</p> <p>Lead: tbc</p> | <ol style="list-style-type: none"> <li>1. Use WHO tools to assess training needs, update training materials and improve regulatory capacity.</li> <li>2. Support adoption of optimal screening technologies and ensure interoperability.</li> <li>3. Assist Member States in developing and implementing effective risk communication strategies.</li> <li>4. Improve availability and usability of WHO knowledge base resources.</li> <li>5. Conduct technical briefings and share best practices between Member States.</li> </ol>                                                                     | <ol style="list-style-type: none"> <li>1. Consolidated list of training needs and updated roster of experts.</li> <li>2(a) WHO guidance on how to select and use technologies to screen for substandard and falsified medical products prepared and published.</li> <li>2(b) At least 10 Member States adopting the Epione tool and maintaining risk-based surveillance data.</li> <li>3(a) Survey and mapping of Member State risk communication activities completed.</li> <li>3(b) WHO guideline on risk communication and awareness published and disseminated.</li> <li>4. WHO guideline on risk-based market surveillance published and disseminated.</li> <li>5. Technical briefings delivered (at least one per year) with participation from Member States.</li> </ol> | <ol style="list-style-type: none"> <li>1. Member States having targeted training and tools to address substandard and falsified medical products.</li> <li>2. Enhanced data collection and risk-based post-market surveillance.</li> <li>3. Improved practices in screening of substandard and falsified medical products in the supply chain.</li> <li>4. Improved awareness and communication to prevent and detect substandard and falsified incidents.</li> </ol> |
| <p>B. Address unregulated distribution channels (via the internet and/or through informal markets) for substandard and falsified medical products</p> <p>Lead: tbc</p>                  | <ol style="list-style-type: none"> <li>1. Build capacity to detect, monitor and respond to substandard and falsified products sold online and through informal markets.</li> <li>2. Develop inter-agency and multisectoral strategies to mitigate risks.</li> <li>3. Pilot and assess the MEDICRAWL tool in detecting substandard and falsified medical product websites and develop a proactive monitoring and coordinated action strategy to combat online distribution and misleading advertising.</li> <li>4. Conduct technical briefings and share best practices between Member States.</li> </ol> | <ol style="list-style-type: none"> <li>1. Strategic guidance document on unregulated channels available by the end of the biennium.</li> <li>2. Country reports on MEDICRAWL findings and recommendations published.</li> <li>3. A proactive monitoring protocol for substandard and falsified product trade and online advertising developed.</li> <li>4. Technical briefings delivered (at least one per year) with participation from Member States.</li> </ol>                                                                                                                                                                                                                                                                                                              | <ol style="list-style-type: none"> <li>1. Member States equipped with strategies, tools and guidance to counter substandard and falsified product distribution via the internet and/or through informal markets.</li> <li>2. Improved cooperation and information sharing among Member States.</li> </ol>                                                                                                                                                             |
| <p>C. Strengthen the supply chain of high-risk excipients and related raw materials</p> <p>Lead: tbc</p>                                                                                | <ol style="list-style-type: none"> <li>1. Conduct a global risk assessment to identify high-risk excipients.</li> <li>2. Map vulnerabilities in manufacturing, distribution and storage.</li> <li>3. Collaborate with Member States, regulatory authorities, industry and United Nations agencies to develop good practices, policies and guidelines.</li> <li>4. Promote data sharing on excipient quality, control and safety.</li> </ol>                                                                                                                                                              | <ol style="list-style-type: none"> <li>1. Risk assessment report and list of high-risk excipients completed.</li> <li>2. Survey and report on Member State practices and policies produced by the end of the biennium.</li> <li>3. Reports on data sharing and control mechanisms published.</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <ol style="list-style-type: none"> <li>1. Improved identification and mitigation of risks in excipient supply chains.</li> <li>2. Increased awareness of substandard and falsified excipient risks through guidelines, training and shared data.</li> </ol>                                                                                                                                                                                                           |

## Annex 2

### Strategic plan

| <b>Member State engagement</b><br>The Member State mechanism is agile and forward-looking, serving as a public forum for discussion and the development of recommendations for policy-makers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Proposed goals</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Proposed actions</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Proposed indicators</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <ol style="list-style-type: none"> <li>1. The Member State mechanism is a critical and valued partner for international organizations and policy forums.</li> <li>2. All WHO regions engage in the work of the mechanism to provide regional data and trends on substandard and falsified medical products, as well as policy coherence.</li> <li>3. All relevant sectors are integrated in a whole-of-government approach to prevent, detect and respond to substandard and falsified medical products.</li> <li>4. All relevant stakeholders at the regional, national and local levels participate holistically to prevent, detect and respond to substandard and falsified medical products.</li> </ol> | <p>The mechanism</p> <ol style="list-style-type: none"> <li>1. Raise the mechanism's profile and improve policy alignment, with the Chair attending relevant policy forums to advocate and communicate on behalf of the mechanism.</li> <li>2. Improve engagement by Member States, especially in respect of Steering Committee roles.</li> </ol> <p>Regional engagement</p> <ol style="list-style-type: none"> <li>3. Improve regional engagement by leveraging regional committee meetings for vice-chairs to present and report on regional substandard and falsified medical product data and communicate alerts about regional trends.</li> <li>4. Establish regional pre- and post-Steering Committee meetings, led by vice-chairs, to solicit input on Steering Committee agenda items.</li> </ol> <p>Policy coherence</p> <ol style="list-style-type: none"> <li>5. Focus on regulatory systems strengthening and multisectoral support, including legal and law enforcement sectors, to address the issue of substandard and falsified medical products adequately and comprehensively.</li> <li>6. Ensure that all handbooks and guidelines emphasize the need for multisectoral collaboration and a whole-of-government approach.</li> <li>7. Foster the inclusion of regional, national and local officials to prevent, detect and respond to substandard and falsified medical products.</li> </ol> | <p>WHO Global Benchmarking Tool indicators<sup>1</sup></p> <ol style="list-style-type: none"> <li>1. RS01.05: Legal provisions and relevant regulations to take actions.</li> <li>2. RS04.03: Rapid alert and recall system.</li> <li>3. MC01.02: Legal provisions and/or regulations authorize market surveillance and control activities.</li> <li>4. MC01.03: Legal provisions and/or regulations address the role of national regulatory authorities.</li> </ol> <p>General progress indicators</p> <ol style="list-style-type: none"> <li>5. The mechanism engages with and develops policy coherence in respect of substandard and falsified medical products with relevant organizations and stakeholders at the regional and international levels.</li> <li>6. The mechanism demonstrates increased collaboration, communication and cooperation with relevant organizations and stakeholders on issues related to substandard and falsified medical products.</li> </ol> |

<sup>1</sup> For detailed information on the indicators, see [WHO Global Benchmarking Tool \(GBT\) for evaluation of national regulatory systems of medical products – Revision VI](#). Geneva: World Health Organization; 2021 (accessed 7 October 2025).

| <b>Technical capacity</b><br>Member States have the tools and resources to prevent, detect and respond to substandard and falsified medical products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Proposed goals                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Proposed actions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Proposed indicators                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <ol style="list-style-type: none"> <li>1. The legitimate medical product supply chain is secured by robust good manufacturing, distribution and pharmacy practices.</li> <li>2. Import and export regulations protect the supply chain from substandard and falsified medical products.</li> <li>3. Accredited laboratories support Member State efforts to prevent and detect substandard and falsified medical products.</li> <li>4. Track and trace systems and end-to-end product security and supply chain solutions are implemented to help to ensure that medical products are legitimate and enhance the detection of substandard and falsified medical products.</li> <li>5. Detection technologies are deployed to survey, monitor and identify substandard and falsified medical products.</li> <li>6. Member States track and respond to substandard and falsified medical products that are sold via the internet and/or through informal markets.</li> </ol> | <p>Supply chain security and regulatory system strengthening</p> <ol style="list-style-type: none"> <li>1. Work with relevant organizations and key Member State focal points on regulatory systems strengthening and capacity-building.</li> </ol> <p>Laboratory testing</p> <ol style="list-style-type: none"> <li>2. Prioritize building national and regional capacity for testing by, for example, including laboratory qualifications as part of meeting WHO Global Benchmarking Tool milestones and/or relevant international standards (for example, ISO/IEC 17025:2017).</li> </ol> <p>Track and trace systems and detection technologies</p> <ol style="list-style-type: none"> <li>3. Support the implementation of WHO handbooks and guidelines on track and trace systems and detection technologies.</li> <li>4. Ensure that handbooks and guidelines include a compendium of available track and trace systems and detection technologies, as well as advisory guidelines for health ministries and national regulatory agencies to work with other sectors to implement/deploy them.</li> <li>5. Consider options for Member States to pool financial and technical resources, etc. in order to access and implement technologies on the ground.</li> </ol> <p>Internet sales and informal markets</p> <ol style="list-style-type: none"> <li>6. Ensure a multisectoral approach to and raise awareness about the sale of substandard and falsified medical products via the internet and/or through informal markets.</li> </ol> | <p>WHO Global Benchmarking Tool indicators</p> <ol style="list-style-type: none"> <li>1. MC01.05: Legal provisions and/or regulations exist for placement of a product's unique identification number.</li> <li>2. MC01.07: Guidelines exist on the recall, storage and disposal of substandard and falsified medical products.</li> <li>3. MC04.07: Documented and implemented procedures and mechanisms exist to prevent, detect and respond to substandard and falsified medical products.</li> <li>4. MC04.08: Documented and implemented procedures and mechanisms to ensure safe storage and disposal of substandard and falsified medical products.</li> </ol> <p>General progress indicators</p> <ol style="list-style-type: none"> <li>5. Capacity is developed to test, track and trace substandard and falsified medical products.</li> <li>6. Member States demonstrate laboratory capacity, as reflected in reaching relevant national regulatory authority maturity levels.</li> </ol> |

| <b>Access to safe, effective, affordable and good quality medical products</b><br>Member States provide and use good quality, comprehensive data to mitigate the harm posed by substandard and falsified medical products, thereby improving access to safe, effective, affordable and good quality medical products |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Proposed goals                                                                                                                                                                                                                                                                                                       | Proposed actions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Proposed indicators                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 1. Member States contribute to and utilize databases with good quality and up-to-date data and fit-for-purpose reporting on substandard and falsified medical products.<br><br>2. Data, experiences and best practices are shared via WHO regional entities or other relevant forums.                                | <p>Reporting and data</p> <p>In order to focus on improving the quality and consistency of data reported to the WHO Global Surveillance and Monitoring System for substandard and falsified medical products and ensure data access and transparency, the Member State mechanism should take the following actions.</p> <ol style="list-style-type: none"> <li>1. Focus on reaching a consensus on data quality, access and transparency standards.</li> <li>2. Reach a consensus on the purpose of Global Surveillance and Monitoring System reporting – for example, whether it is for event management or knowledge generation.</li> <li>3. Work with the Secretariat to ensure that the Global Surveillance and Monitoring System pulls data from existing reporting systems for substandard and falsified medical products to reduce the duplication of reporting and improve the breadth of data collection.</li> <li>4. Consider regional working groups to support and underpin improvements in data reporting and information sharing.</li> <li>5. Train Member State focal points in the importance of reporting consistent and fit-for-purpose data.</li> <li>6. Establish reporting mechanisms that both share and collect data on incidents of substandard and falsified medical products as reported by the public, health workers and/or relevant stakeholders.</li> </ol> <p>Sharing data and best experiences</p> <ol style="list-style-type: none"> <li>7. Consider the impacts of regulation and surveillance on access to substandard and falsified medical products.</li> </ol> | <p>WHO Global Benchmarking Tool indicators</p> <ol style="list-style-type: none"> <li>1. MC04.05: Documented and implemented procedures exist to enable the public to report substandard and falsified medical products.</li> <li>2. MC06.02: Findings and regulatory decisions are communicated to all national stakeholders, including the public.</li> <li>3. MC06.03: Findings and regulatory decisions are communicated and shared with other countries and regional and international organizations.</li> </ol> <p>General progress indicators<sup>1</sup></p> <ol style="list-style-type: none"> <li>4. An increased number of national regulatory authorities are reporting substandard and falsified medical products to the Global Surveillance and Monitoring System.</li> <li>5. Post-marketing surveillance indicators are developed.</li> </ol> |

---

<sup>1</sup> Working Group B plans to develop performance indicators for the functionality of Member State focal points.