World Health Organization

**TENTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS**
**Provisional agenda item 6**

**A/MSM/10/6**
**7 October 2021**

# Draft list of prioritized activities to implement the workplan of the Member State mechanism for the period 2022–2023

## BACKGROUND

1. In May 2014, the Sixty-seventh World Health Assembly noted the agreed eight-point workplan of the WHO Member State mechanism on substandard and falsified medical products contained in document A67/29 (Appendix 2).[1] Since 2014, the Member State mechanism has agreed on a biennial list of prioritized activities to implement the workplan. The current list of prioritized activities covers the biennium 2020–2021, and the next list of prioritized activities, for 2022–2023, will be considered at the tenth meeting of the Member State mechanism during the week of 25–29 October 2021. In October 2020, the Member State mechanism called for the creation of five new working groups to support Activities B (global focal point network), C (detection technologies), E (risk communication and awareness), F (impact and advocacy), and regional and global initiatives.[2] Four working groups exist for Activities A (risk-based post-market surveillance), C ("track and trace"), G (transit) and H (internet).

2. On 29–30 June and 17 September 2021, the Steering Committee discussed the progress of implementation of the list of prioritized activities for 2020–2021 and the drafting of the next list of prioritized activities, for 2022–2023. The Committee agreed on the following items:

1. Two prioritized activities for 2020–2021, Activity D (access) and Activity G, will be completed by the plenary meeting and are therefore proposed for deletion.

2. Continuation of work is supported for Activities A, B, C, E, F and H in the next list of prioritized activities.

3. Pursuit of work on strengthening engagement and advocacy in various international forums is supported in the context of a single working group under Activity F (with the understanding that the Secretariat will continue to report on regional and global initiatives).

4. Integration of a new prioritized activity on informal markets is supported.

5. The current list of prioritized activities is too technical and needs to be more strategic and policy focused.

[1] See the summary records of the Sixty-seventh World Health Assembly, Committee B, fourth meeting, section 2 (document WHA67/2014/REC/3).

[2] Document A/MSM/9/7.

6. The current list of prioritized activities is output-centric and needs to be more outcome-oriented.

3. To inform the Steering Committee's considerations, the Secretariat also noted the following points:

- Terms of reference are still to be drafted for eight working groups (including the merged working group and five new working groups); as such, it is proposed that the Steering Committee set outcomes and strategic objectives, but empower the working groups to determine actions.

- The 2020–2021 prioritized activities align with seven of the twelve actions of the global prevention, detection and response strategy described in the report *WHO Global surveillance and monitoring system for substandard and falsified medical products*,[1] which is adapted from the Member State mechanism guidance on developing national and regional plans for preventing, detecting and responding to substandard and falsified (SF) medical products contained in document A70/23 (Appendix 1).

## Current status

4. The present document contains the draft list of prioritized activities for 2022–2023 recommended by the Steering Committee for consideration by Member States. The following items are also proposed for the consideration of Member States (see the annex to this document):

- three public health outcomes that align to the goals and objectives of the Member State mechanism set by the Sixty-fifth World Health Assembly in resolution WHA65.19 (Annex);

- three strategic prioritized activity areas with seven corresponding indicators that align with the workplan of the Member State mechanism contained in document A67/29 (Appendix 2) and with the global prevention, detection and response strategy.

5. The the following changes were made to the list of prioritized activities for 2022–2023.

- Amendment of the prioritized activities to include:

  - removal of specific mention of the Global Focal Point Network to open the opportunity to facilitate cooperation and collaboration with other stakeholder networks;

  - addition of the new Member State lead for Activity B;

  - update of Activities C and E to reflect a more outcome-focused objective;

  - removal of completed Activities D and G;

[1] WHO Global surveillance and monitoring system for substandard and falsified medical products, pp 46–7. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/bitstream/handle/10665/326708/9789241513425-eng.pdf?sequence=1&isAllowed=y, accessed 23 September 2021).

  - addition of a new prioritized activity to implement the recommendations outlined in paragraphs 19–20 of A/MSM/9/6 (continuation of 2020–2021 Activity D);

  - addition of a new prioritized activity on informal markets.

- Amendment of the Status column to reflect updated status.

- No changes to the Actions column, with the understanding that:

  - In accordance with the Update on the list of prioritized activities for 2020–2021 (Agenda item 4), the current Actions are in various stages of progress, with some due to be completed by the next plenary meeting. They should thus be reviewed and amended, as necessary.

  - The eight working groups should be empowered to determine their respective actions in line with the proposed prioritized activities.

  Addition of a column for Alignment to strategic prioritized activity areas, with alignment to the proposed indicators as relevant.

| Prioritized activities | Status | Actions<br>Note: The 2022–23 actions are proposed to be determined by the respective Prioritized Activity lead and working group members. At this stage, no changes have been made to the agreed 2020–2021 actions. | Alignment of actions to strategic prioritized activity areas (Annex 1) |
|---|---|---|---|
| A. Strengthen the capacity of national/regional regulatory authorities for the prevention and detection of, and response to, substandard and falsified medical products.<br><br>Lead: Brazil, with the support of the Secretariat | In progress | 1. Develop training material for national/regional regulatory authorities, focused on promoting the technical and knowledge documentation approved by the Member State mechanism. | 1. 3.1 |
| | | 2. Assist in the identification of the training needs, existing expertise and training materials of Member States and other institutions in order to build capacity concerning the prevention and detection of, and response to, substandard and falsified medical products. | 2. 3.1 |
| | | 3. Risk-based post-market surveillance: | |
| | | (a) Develop tools and a database to automate the conduct of medical products quality surveys and enhance the quantity and quality of data captured to inform risk-based post-market surveillance programmes based on existing WHO guidance. | 3a. 2.3 |
| | | (b) Develop guidance documents to strengthen capacities of national/regional regulatory authorities to plan, perform, and assess risk-based post-market surveillance including the effective use of the tools. | 3b. 2.3 |
| B. Develop, expand and maintain global networks of stakeholders to facilitate cooperation and collaboration.<br><br>Lead: Eritrea, with the support of the Secretariat | In progress | 1. Continue to follow up with Member States to nominate focal points. | 1. 2.2 |
| | | 2. Continue to train new focal points and provide refresher training for existing focal points. | 2. 2.2 |
| | | 3. Facilitate the exchange of information in the Global Focal Point Network. | 3. 2.2 |

| | Prioritized activities | Status | Actions<br>Note: The 2022–23 actions are proposed to be determined by the respective Prioritized Activity lead and working group members. At this stage, no changes have been made to the agreed 2020–2021 actions. | Alignment of actions to strategic prioritized activity areas (Annex 1) |
|---|---|---|---|---|
| C. | Improve Member States' understanding and uptake of technologies to screen and detect SF medical products, and implementation of national traceability systems.<br><br>Lead: TBC with the support of the Secretariat | In progress | 1. Convene open-ended expert sessions to review existing field detection devices and "track and trace" models, and, as needed:<br>(a) provide updates on existing "track and trace" and authentication technologies in use by Member States; and<br>(b) report on existing field detection devices in use or available to Member States.<br>2. Working group to continue to develop the policy paper on "track and trace" and submit a finalized document to the Member State mechanism. | 1a. 1.2<br><br>1b. 2.1<br><br>2. 1.2 |
| D. | Leverage the competencies of relevant stakeholders, including policy-makers, procurers, distributors, practitioners, patients and consumers, to reduce the burden of SF medical products, including good governance.<br><br>Lead: TBC with the support of the Secretariat | Proposed | 1. Develop a handbook to accelerate sustainable implementation, monitoring and evaluation of national prevention, detection and response strategies on substandard and falsified medical products. | 1.1 3.1 |

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|---|---|---|---|
| E. Enhance Member States' capacity to run effective risk communication campaigns for substandard and falsified medical products.<br><br>Lead: TBC with the support of the Secretariat | In progress | 1. Conduct surveys on patient or consumer attitudes and behaviours on accessing medical products in four African countries, and<br>(i) develop or leverage recommendations for effective risk communication and awareness campaigns;<br>(ii) produce samples of hard and soft copy material and video and broadcast material;<br>(iii) assess the use of social media for raising awareness;<br>(iv) identify the full range of stakeholders and audiences; and<br>(v) develop key and innovative advocacy material.<br>2. Pilot the implementation of a compulsory element in the pharmacy school curriculum in five African countries. | 1i–v. 1.3<br><br>2. 1.3 |
| F. Enhance Member States' capacity to expand awareness, effectiveness, impact and outreach in their work on substandard and falsified medical products.<br><br>Lead: TBC with the support of the Secretariat | In progress | 1. Secretariat, working with Member States, to enable a proactive approach to disseminate and promote the materials and information developed by the Member State mechanism.<br>2. Member States to use documentation developed by the Member State mechanism and WHO reports as tools to increase political awareness and advocacy at the highest policy levels about the need to support and dedicate resources to prevent, detect and respond to substandard and falsified medical products. | 1. 1.1<br><br>2. 1.1 |

| | Prioritized activities | Status | Actions<br>Note: The 2022–23 actions are proposed to be determined by the respective Prioritized Activity lead and working group members. At this stage, no changes have been made to the agreed 2020–2021 actions. | Alignment of actions to strategic prioritized activity areas (Annex 1) |
|---|---|---|---|---|
| G. | Identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet.<br>Lead: Colombia | In progress | 1. A working group was established to:<br>(a) develop terms of reference (completed);<br>(b) provide a problem statement identifying the range of issues that facilitate the sale and supply of substandard and falsified medical products through the internet both nationally and across borders (completed);<br>(c) identify experiences or regulation of the distribution or supply of medical products via the internet to prevent and reduce the risk of substandard and falsified medical products reaching consumers; and<br>(d) develop guidance on strategies to enable national/regional regulatory authorities to address the distribution or supply of substandard and falsified medical products via the internet. | 1a–d. 2.3 |
| H. | Develop strategies for National Regulatory Authorities to mitigate public health risks posed by distribution of SF medical products through the informal markets.<br>Lead: TBD | New | To be determined by the respective Member State lead, including developing a working definition of informal markets | 2.3 |

ANNEX

# PUBLIC HEALTH OUTCOMES AND STRATEGIC PRIORITIZED ACTIVITY AREAS

**Public health outcomes**

1. Increased technical capacity
2. Improved access to safe, effective, affordable and quality medical products
3. Strengthened governance

## Strategic prioritized activity area 1: Prevention

1.1 Increase multistakeholder engagement to maximize impact and outreach, including through regional and global networks and collaboration across both strategic areas of the "Roadmap for access to medicines, vaccines and health products 2019–2023: comprehensive support for access to medicines, vaccines and other health products".[1]

1.2 Increase supply chain integrity including by improving Member States implementation of national traceability systems and strategies to mitigate risks of the informal markets[2] to sell or distribute medical products.

1.3 Promote effective education and awareness for relevant stakeholders, including non-health professionals, the general public and civil society groups.

## Strategic prioritized activity area 2: Detection

2.1 Increase access and uptake of technologies for screening and detecting substandard and falsified (SF) medical products, testing including by improving Member States understanding of detection and screening technologies.

2.2 Increase reporting of SF medical products by healthcare professionals and general public to national regulatory authorities (NRAs) and by NRAs to national, regional and global networks, including the WHO Global Surveillance and Monitoring System and the WHO Global Focal Point Network.

2.3 Promote a risk-based strategy for NRAs to conduct market surveillance for substandard and falsified medical products within the regulated and unregulated supply chains, including the internet and the informal markets.[2]

## Strategic prioritized activity area 3: Response

3.1 Strengthen the capacity of national/regional regulatory authorities to respond to incidents of substandard and falsified medical products, including engaging in relevant partnerships such as with law enforcement and customs authorities.

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[1] The strategic areas include: (1) Ensuring quality safety and efficacy of health products; (2) Improving equitable access.

[2] Working definition of informal markets to be established by the working group.