

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

Strengthen the capacity of national/regional regulatory authorities for the prevention and detection of, and response to, substandard and falsified medical products

Executive summary linked to Activity A

BACKGROUND

1. The list of prioritized activities to implement the workplan of the Member State mechanism for the period 2024–2025 includes Activity A to strengthen the capacity of national/regional regulatory authorities for the prevention and detection of, and response to, substandard and falsified medical products. Action 1 for prioritized Activity A aims to use global standard tools to assist in the identification of training needs and existing expertise for Member States in order to prevent, detect and respond to substandard and falsified medical products. The present executive summary describes a study that was commissioned by the WHO Secretariat in order to identify common gaps in market surveillance and control of medical products.
2. The study, a cross-sectional analysis of benchmarking data from national health authorities between 2016 and 2024, was conducted using the WHO Global Benchmarking Tool. This tool enables national regulatory authorities to evaluate and enhance their regulatory systems by identifying strengths, addressing weaknesses and prioritizing improvements. The various functions of the systems are measured on the basis of a maturity scale in which each of the four levels used indicates the extent to which an organization has implemented and institutionalized WHO benchmarking principles. After using the Global Benchmarking Tool, national regulatory authorities develop an institutional development plan aimed at achieving maturity level 3 or above, indicating a stable and well-integrated regulatory system.
3. The market surveillance and control regulatory function applies to all medical products and is cross-linked to eight other functions and their corresponding performance indicators. Activities related to this function are primarily concerned with four themes: (1) control of import activities; (2) prevention and detection of and response to substandard and falsified medical products; (3) market surveillance programmes for monitoring the quality of medical products throughout the supply chain; and (4) control of promotional, marketing and advertising activities.
4. The global nature of the medical product supply chain complicates regulatory oversight and control, posing significant challenges for national regulatory authorities. Notifications recorded in the WHO Global Surveillance and Monitoring System for substandard and falsified medicines highlight the problem of inadequate resources in national regulatory authorities, including lack of skilled human

resources and essential processes and tools for effective market surveillance. These gaps, particularly for national regulatory authorities operating below maturity level 3, undermine the ability to ensure the safety and quality of medical products, ultimately affecting public health outcomes. Identifying and addressing these common deficiencies is crucial for improving regulatory effectiveness.

OBJECTIVES AND METHODS

5. The study aimed to identify common critical gaps, highlight high priorities in institutional development plans for market surveillance and control activities and propose some recommendations for the Member State mechanism, national regulatory authorities and WHO on follow-up actions.

6. A cross-sectional analysis was conducted of various indicators from formal WHO benchmarking outcomes and institutional development plans. The analysis highlighted common critical gaps to be addressed, as well as the needs of national regulatory authorities, from regional and global perspectives, that are necessary to be met in order to achieve maturity level 3.

7. The study targeted only those national regulatory authorities that were formally assessed by WHO based on 57 cross cutting sub-indicators up to maturity level 3 during the period 2016 to 2024. Those at maturity level 4 were excluded from the analysis. Data were standardized and harmonized to a common format to facilitate the identification of the common gaps to prioritize the necessary resources, and areas for support at national, regional and global level required to strengthen market surveillance and control activities.

8. All 35 national regulatory authorities formally benchmarked during the period 2016 to 2024 up to maturity level 3 within the scope of medicines and vaccines were included: 14 in the African Region, one in the Region of the Americas, three in the European Region, six in the South-East Asia Region, four in the Eastern Mediterranean Region and seven in the Western Pacific Region. One national regulatory authority had two separate benchmarking files, for medicines and for vaccines (producing country) scopes.

9. The WHO computerized Global Benchmarking Tool (cGBT versions 12 and 13) was used to extract the records of the sub-indicators that were noted as “not implemented, ongoing implementation, partially implemented and implemented”. All institutional development plans entered at the level of each of the sub-indicators were also extracted. Microsoft Excel was used for the cross-sectional analysis of extracted data.

10. The data were collected using specific search criteria for the institutional development plans identified from the 57 sub-indicators relevant to the market surveillance and control function spanning through each of the nine regulatory functions. The plans were further categorized into nine themed activity types.

11. The status of implementation of each of the 57 sub-indicators was sorted by country, WHO region, scope of benchmarking and overall maturity level.

RESULTS

12. A total of 1213 institutional development plans from the 35 benchmarked national regulatory authorities were standardized and consolidated into 295 institutional development plans, addressing nine themed activity types from nine regulatory functions.

13. Analysis across the six regions of WHO shows that 64% of national regulatory authorities are operating below maturity level 3, indicating weak or evolving systems for market surveillance and

control activities. Of the institutional development plans developed and agreed to with the benchmarked regulators, 54.7% have been implemented, while 45.3% remain unimplemented. The percentage of unimplemented plans among the regions ranges from 20% in the Americas to 68% in the Eastern Mediterranean, with South-East Asia at 60%, the Western Pacific at 52%, Africa at 35% and Europe at 26%.

14. Analysis of the 57 cross-cutting sub-indicators across all nine regulatory functions reveals that the most critical areas (percentage of benchmarked national regulatory authorities) requiring further support to the national regulatory authorities and stakeholders are market surveillance and control (53%), vigilance (17%), regulatory inspection (14%), laboratory testing (10%) and national regulatory systems (6.4%). The support required includes the development and updating of procedures, legal frameworks and guidelines; increased investment in information technology and information management systems; and ensuring effective coordination and communication among Member States, stakeholders and international organizations.

15. The 295 consolidated institutional development plans from all national regulatory authorities were analysed and ranked by frequency of occurrence, leading to the identification of 18 high-priority gaps. These gaps will serve as the primary basis for recommendations to stakeholders, including Member States, WHO and other relevant entities.

16. The study further identified common critical market surveillance and control regulatory gaps and highlighted priorities to address them to facilitate the attainment of maturity level 3 by national regulatory authorities.

CONCLUSIONS

17. The findings of this study offer valuable insights for the Member State mechanism, Member States and their national regulatory authorities, WHO and stakeholders. By addressing the critical and high-priority gaps identified in the full study report,¹ these entities can significantly enhance the effectiveness of their market surveillance and control functions towards long-term impact outcomes. The study underscores the urgent need for coordinated as well as collaborative local and global actions to achieve these outcomes.

ACTION BY THE MEMBER STATE MECHANISM

18. The mechanism is invited to note the executive summary. In its discussions, it is further invited to provide comments and guidance in respect of the following questions:

- How can Member States and WHO prioritize actions to address high-priority gaps in market surveillance and control, especially in regions with low implementation rates for institutional development plans?
- What steps can be taken to help national regulatory authorities below maturity level 3 to improve market surveillance and control, with a focus on information technology, legal frameworks and stakeholder communication?

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¹ To be available in the first quarter of 2025 at https://www.who.ints/health-topics/substandard-and-falsified-medical-products#tab=tab_1.