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

Improve Member States' understanding and uptake of technologies to screen and detect substandard and falsified medical products

Executive summary linked to Activity C

1. The list of prioritized activities to implement the workplan of the Member State mechanism for the period 2024–2025 includes Activity C to improve Member States' understanding and uptake of technologies to screen and detect substandard and falsified medical products. This activity is led by Montenegro. The present executive summary has been produced in the light of the work of the working group on detection technologies, which, under action 2 of its remit,¹ has focused on collating existing methodologies/tools used to screen and detect substandard and falsified medical products.

BACKGROUND

2. In terms of detecting substandard and falsified medical products, methods conducted within laboratory settings are considered to be the gold standard. In low- and middle-income countries, stakeholders often rely solely on visual inspection to identify circulating substandard and falsified medical products. Samples are subsequently sent for analysis in medicine or vaccine quality control laboratories, utilizing validated pharmacopeial protocols specific to active pharmaceutical ingredients and dosage formulations. In cases where pharmacopeial methods are unavailable, non-validated in-house procedures, such as high-performance liquid chromatography, may be employed. However, such tests are costly, time-consuming and often scarce in many countries, leading to significant delays between the collection of suspicious medicines and the confirmation of their poor quality. This delay allows harm to spread unchecked in the interim.

3. To gain a better understanding of which methodologies and tools are being used to detect substandard and falsified medical products, the working group on detection technologies developed a survey to gather information on the current technologies available and the accompanying procedures and legal provisions. The survey was sent to all Member States. The original survey deadline was extended to December 2023 and the analysis of the responses was completed in early 2024.

¹ This work started under the workplan for the period 2022–2023. Activity C originally had two working groups (one on detection technologies and one on traceability). These two working groups were subsequently separated for the period 2024–2025. The remit of the working group on detection technologies remained under Activity C.

METHODS

4. All Member States were invited to participate in the questionnaire, which was made available in the six United Nations languages. A total of 85 Member States responded, of which 23 provided full responses and 62 incomplete responses.
5. Questions were grouped into the following topics:
 - (a) regulatory documentation to support the use of detection technologies;
 - (b) roles and responsibilities for the use of detection technologies;
 - (c) type of testing conducted using detection technologies;
 - (d) detection technologies used for substandard and falsified medical products;
 - (e) challenges for the sustainable implementation of detection technologies for substandard and falsified medical products; and
 - (f) types of substandard and falsified medical products identified by detection technologies.

RESULTS

6. The survey responses show that a variety of technologies for the detection of substandard and falsified medical products are used across Member States. The survey underscores the need for enhanced legal frameworks, better-defined procedures, increased technical capacity and more comprehensive regulation of supply chains to effectively combat the issue of substandard and falsified medical products.
7. Notably, just 13 of the responding Member States have legal provisions for detecting substandard and falsified medical products and eight reported no procedure for technologies to screen and detect substandard and falsified medical products at all. National regulatory authorities primarily aim to detect falsified products and control quality defects not identified during production and release. Detection of substandard and falsified products is often reactive, with 20 Member States conducting testing based on alerts from law enforcement or other national regulatory authorities; while 12 Member States proactively sample their market, indicating more advanced systems with greater resources. Common detection laboratory technologies include high performance liquid chromatography, ultraviolet-visible spectrophotometry, thin layer chromatography and infrared spectroscopy, while field technologies include the GPHF-MiniLabTM, paper analytical devices and near infrared spectroscopy.
8. Effective detection technologies must be usable close to where substandard and falsified products are found and should ideally not require electricity, complex calibration or internet connection. Technologies that confirm substandard and falsified medical products must be highly specific to avoid unnecessary recalls and public worry. Major challenges include insufficient technical and/or regulatory knowledge, lack of funding and unregulated supply chains.
9. Once finalized, the full report of the survey containing more substantive information will be made available to Member States. Furthermore, the results of the survey will be used as a landscape analysis of detection technologies for forthcoming WHO normative guidance on how to select and use technologies to screen and detect substandard and falsified medical products.

ACTION BY THE MEMBER STATE MECHANISM

10. 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 be supported in their decision-making processes when deciding which detection technology to procure?
- Which considerations should be taken into account when conducting testing for reported quality defects as compared to testing undertaken as part of risk-based post-market surveillance?

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