

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

Improve Member States' implementation of national traceability systems

Executive summary linked to Activity J

BACKGROUND

1. The list of prioritized activities to implement the workplan of the Member State mechanism for the period 2024–2025 includes Activity J to improve Member States' implementation of national traceability systems. This activity started under the workplan period 2022–2023 as part of Activity C.¹ Activity C had two working groups (on detection technologies and on traceability) that have been separated for the period 2024–2025. The work carried out by the working group on traceability is now Activity J, which is led by Nigeria.²

2. Traceability systems make it possible to trace medical products throughout the supply chain – from the final stage of manufacture to the point of dispensing or the place where the medical product is administered to a patient or individual – with a view to strengthening real-time monitoring. There is global recognition that traceability systems can be leveraged as a tool to ensure product integrity and improve the efficiency of supply chains. Traceability may not be able to completely stop substandard and falsified medical products from entering the supply chain but if successfully implemented, traceability systems can minimize the risk of such products entering the supply chain and allow for earlier detection and response.

3. To gain a better understanding of the experiences of countries that have implemented traceability systems for medical products, the working group on Activity J developed a survey to collect information in a standardized manner.

SURVEY RESULTS

4. All Member States were invited to complete an online questionnaire, which was made available in the six official languages of WHO.

¹ See document A/MSM/10/11 Rev.1, Annex 2.

² See document A/MSM/12/10.

5. The questionnaire covered the following topics:
 - (a) overall governance
 - (b) roles and responsibilities
 - (c) challenges faced by Member States
 - (d) status of implementation of traceability systems
 - (e) standards required for optimal implementation of traceability systems
 - (f) data governance.
6. A total of 64 Member States responded (by the deadline of 15 December 2023): 16 provided full responses; the responses of 48 were incomplete.
7. The implementation of national traceability systems varied significantly among the Member States that responded:
 - (a) six had operational systems for tracking medical products throughout the supply chain;
 - (b) seven were planning such systems; and
 - (c) five had no plans to implement traceability systems.
8. The primary reason given by Member States for implementing a traceability system was most commonly for oversight of the security of the supply chain, allowing real-time product tracking, recalls and withdrawals. Eight Member States of the 16 that responded in full had established regulations for traceability.
9. In terms of governance, Member States reported clear delineation of roles and responsibilities between government entities and private-sector participants in their traceability system, with the government assuming the primary responsibility for most aspects: data ownership, access rights, set-up and maintenance funding, interoperability requirements, system design changes, new technologies and system changes, and response to signals of substandard and falsified medical products. Shared responsibility between government and businesses participating in the supply chain and vendors was foreseen for access rights and set-up and maintenance funding.
10. Member States identified some challenges in implementing and maintaining effective traceability systems, with the following emerging as the most common:
 - (a) insufficient funding to move forward with implementing and/or for enforcement; and
 - (b) limited technology capability at ports of entry, distribution centres and pharmacies in remote areas (regarding, for example, internet service, cellular data service, barcode readers, smartphones and computers).

11. Member States identified the following challenges as being of moderate concern:
- (a) insufficient recognition or understanding of the problems arising from substandard and falsified medical products or how they might be solved by traceability;
 - (b) supply chains for health care products were generally not fully regulated;
 - (c) insufficient technical knowledge in the government to develop workable regulation;
 - (d) confusion over which traceability approach and/or which standards would yield the best protections at the lowest cost; and
 - (e) an immature regulatory environment.
12. Only a few Member States reported the following challenges:
- (a) opposition from stakeholders (such as manufacturers, importers, international procurement agencies, distributors and pharmacies); and
 - (b) limited support from vendors.
13. Costs related to hardware and software can be foreseen and quantified but the overall cost of operating a traceability system with adequate follow-up of signals and enforcement has yet to be fully quantified. There is a perceived risk that the costs of implementing traceability may be passed on to consumers as stakeholders have insufficient capacity to make the necessary long-term investments. Cost savings that may be generated by implementation of traceability systems must also be estimated and considered as part of costing exercises.
14. Various types of standards are required for optimal implementation of traceability systems, including data coding standards for data carriers, such as barcodes, data matrix, shipping items and geographical locations. Ten Member States of the 16 that responded in full used global standards only, four used both global and domestic standards, and one used domestic standards only. This demonstrates the need for traceability systems that allow for interoperability, given the mix of global and domestic standards. Seven Member States of the 16 that responded in full used a two-dimensional data matrix, four used linear barcodes and two used radio-frequency identification.
15. Once finalized, the full survey results will be made available to Member States.

ACTION BY THE MEMBER STATE MECHANISM

16. 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.
- In what specific areas can the Secretariat support the implementation of traceability systems while complementing the work of the Member State mechanism and the working group on Activity J?
 - Considering the expected increase in signals from national traceability systems, what role can Member States play in supporting the WHO Global Surveillance and Monitoring System's capacity-building efforts?

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