World Health Organization

NINTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS
Provisional agenda item 3

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Secretariat activites and budget to implement the workplan of the Member State mechanism

Update by the Secretariat

BACKGROUND

1. WHO has a dual approach to dealing with substandard and falsified medical products. In addition to the Member State mechanism, which is an intergovernmental process, WHO has a dedicated technical team that directly supports Member States addressing substandard and falsified medical products.

2. Preventing, detecting, and responding to substandard and falsified medical products requires careful coordination and sound strategies. In order to develop an appropriate evidence base, WHO launched the Global Surveillance and Monitoring System for substandard and falsified medical products in July 2013. The Global Surveillance and Monitoring System forms the foundation for technical guidance to Member States and bespoke capacity-building approaches. It works with Member States to improve the quantity, quality and analysis of data on substandard and falsified medical products, and to analyse that data in order to provide information and knowledge that Member States can apply to protect public health.

3. Trained focal points inform the database of the Global Surveillance and Monitoring System in a structured and standardized fashion. In the short term, the WHO technical team provides incident management support to protect public health. In the long term, the data are analysed to identify national/regional needs, driving forces and impact opportunities, ultimately informing policy and processes with a public health outlook. The growing quality and quantity of records in the database allow for more granular analyses and targeted interventions. The key components of the Global Surveillance and Monitoring System (as a holistic system) include the database of validated evidence, the online portal, analytical knowledge products, focal point networks, operational projects, and communication and alert routes. The alerts issued via the Global Surveillance and Monitoring System and the networks of focal points have been recognized as global public health goods for the purposes of the Thirteenth General Programme of Work, 2019–2023.

4. The list of prioritized activities established by the Member State mechanism is aligned with the projects and background work delivered via the Global Surveillance and Monitoring System and the WHO technical team. This document provides an update on those activities which do not fall within the mechanism's 2019–2020 workplan, but are nonetheless directly linked to it.

General update: new team structure and WHO transformation

5. In 2017, the Director-General launched the WHO transformation agenda, with the goal of making WHO a modern, seamless, impact-focused organization better able to help Member States achieve the health-related Sustainable Development Goals in the context of United Nations reform. The programmes

pillar coordinates and delivers WHO's technical work in line with two of the Thirteenth General Programme of Work's "triple billion" goals, namely: healthier populations and universal health coverage. The Access to Medicines and Health Products Division is situated within this pillar.

6. In December 2019, the Director-General approved the Division's new organization chart, establishing the structure of the Regulation and Pre-Qualification Department and the Regulation and Safety Unit. The Global Surveillance and Monitoring System is managed by the incidents and substandard and falsified medical products (ISF) team within the Regulation and Safety Unit. The ISF team is also responsible for internal referrals and coordination of incoming incidents and complaints with the relevant division teams (the operational details of this arrangement are still being finalized). Structurally aligned with the WHO transformation approach, the team's workflow concept focuses on services provided to Member States and impact delivery. The ISF team now comprises eight full-time staff positions (six short-term and two permanent), supported by two operational consultants.

Update on IT improvements to the Global Surveillance and Monitoring System

7. The Global Surveillance and Monitoring System is supported by tailored software that was long overdue for an upgrade. The upgrade provided an opportunity to revise the data architecture and internal processes for handling incidents and complaints received, managed and/or allocated by the ISF team. It has three major phases: (i) software upgrade and data migration (completed); (ii) enhancements and development of new functions (ongoing); and (iii) connection to other datasets or systems (not started).

8. The Global Surveillance and Monitoring System receives incoming data via an online platform or portal. The portal allows focal points to report incidents, search parts of the back-end database and browse various resources (including contact details of official nominated members of the focal point network). In the face of mounting cyberthreats, portal access has been further secured, with multifactor authentication and new profiles created for every portal user – a measure that has unfortunately delayed the portal's go-live. The new portal will also enable authorized third parties to report incidents to the Global Surveillance and Monitoring System without accessing the other functionalities. The portal will be further improved in the coming year: multiple languages will become available; the resources section will be expanded to include distance training material; and user feedback will be analysed and implemented.

9. This upgrade reflects a structured approach to simplified and standardized data collection, which will enhance both the quality of reports and the resulting analysis.

Update on global medical product alerts

10. In October 2020, the database held over 2700 records of substandard and falsified medical products and had issued 40 global medical product alerts. All alerts are designed to increase national and regional market surveillance – in many cases, this leads to the discovery of other substandard and falsified versions of the medical products described in the alert. Alerts are translated into the six WHO official languages, are publicly available on the ISF team webpages and are actively distributed through the networks of focal points.

11. Between January and September 2020, the Global Surveillance and Monitoring System issued five medical product alerts, covering products identified in all regions. Medical Product Alert No. 2/2020 is the first issued by the Global Surveillance and Monitoring System regarding falsified in vitro diagnostics (IVD); the ISF team also issued four information notices for users of IVD.

12. More than half of communications for the general public (global alerts and information notices) issued via the ISF team so far in 2020 reference medical products in relation to COVID-19 (therapeutics of interest, IVD, etc.). Since February 2020, the Global Surveillance and Monitoring System has recorded over 40 substandard and falsified medical products (including vaccines and IVD) that have an established link to the ongoing COVID-19 pandemic. Some of the falsified products imitate existing (genuine) products, while others are "miracle cures". Underreporting is considered highly likely, across all regions and product types.

UPDATE ON FIELD SURVEYS AND POST-MARKET SURVEILLANCE ACTIVITIES

Update on first series of field surveys on antimicrobial quality

13. Acquiring reliable knowledge on the structure and dynamics of markets for medical products can be a lengthy and costly process – but is also a prerequisite for sound and cost-efficient regulatory measures. The ISF team has therefore initiated a series of surveys aimed at: (i) establishing the quality of selected medicines circulating in the field and understanding the dynamics between substandard and falsified medical products and antimicrobial resistance; (ii) leveraging technology, in particular by assessing and improving detection methods, including field screening equipment and laboratory networks; and (iii) strengthening regulatory authorities by capturing data and analysing operational processes in order to streamline and lower the costs of post-market surveillance.

14. Systematic market surveys (with standard procedures) have been completed in six countries (Benin, Ghana, Nigeria, Sierra Leone, Togo and Uganda) in the African Region. Just under 1800 samples of antibiotics, antimalarials and reproductive health products were collected in over 400 outlets/locations over a period of five months. All the samples were inspected and triaged (decision process); a near-infrared device was tested as a triage tool for some categories of products. Only 25% of the samples were sent for compendial analysis (including assay, dissolution and uniformity) to one of six selected and contracted laboratories. Of those samples, over 40% failed at least one of the analytical tests to determine product quality. Over two thirds of all the samples collected were antibiotics. The vast majority (82%) was collected at patient level (including in the public and private sectors, hospitals, clinics, dispensaries, pharmacies and unregulated markets).

15. The project was delayed at different points for reasons relating to fund transfers, customs clearance, testing methodology validations and COVID-19 restrictions. Further investigation will determine whether the samples are substandard or falsified, but from a public health perspective, in either case, once the product has reached the patient it is equally harmful in terms of increased mortality and morbidity, antimicrobial resistance spread and failed trust in health systems.

16. The findings of, and lessons learned from, this activity directly inform the design and development of risk-based post-market surveillance tools. This is linked to Prioritized Activity A, Action 3, on the agreed list of prioritized activities to implement the Member State mechanism's workplan (2020–2021).

17. Data collected during the surveys will also inform a parallel project lead by another WHO technical team to develop an online reference library and database for monitoring and verifying the claimed quality of pharmaceutical products and detecting any substandard and falsified versions. The project outcome will be called the WHO Global Medicines Spectral Data Analysis Solution (MeSDAS).

Update on post-market surveillance of medical devices

18. Monitoring the globalized markets for raw materials and finished medical products requires effective coordination of diverse players in a technically challenging field. Post-market surveillance ensures that patients receive medical products that meet appropriate and agreed standards. It is a core regulatory function and a key indicator of the WHO Global Benchmarking Tool.

19. However, the last mile of the supply chain is the least supervised: the increasing number of transactions heightens the risk that substandard and falsified medical products reach patients. The people conducting post-market surveillance are often underresourced and insufficiently interconnected; this is especially true in the case of medical devices, which are not subject to the same regulatory environments as medicines. For these products, post-market surveillance may be conducted by the manufacturers and may highlight opportunities to improve the medical device.

20. The WHO Global Model Regulatory Framework for Medical Devices, including IVD medical devices, like many other international regulatory frameworks, requires the implementation of post-market surveillance systems.[1] Through its normative guidance; the WHO Secretariat helps Member States to improve post-market surveillance by users and regulators. In 2015, WHO issued guidance on post-market surveillance of IVD:[2] this document is currently being updated to include all medical devices, in close coordination with other WHO teams dealing with regulation and disease programmes, and with relevant technical experts.

21. More generally, WHO works to improve the quality control of IVD materials, specifically for SARS-CoV-2 nucleic acid testing, HPV nucleic acid testing, and other bloodborne viruses such as HIV and hepatitis. This is an opportunity to leverage the WHO IVD complaint database for prequalified IVD products (in operation since 2015, holding over 200 complaints) and cross-reference it with the database of the Global Surveillance and Monitoring System.

Update on the pilot project "reporting application and process"

22. A WHO smartphone application, designed to enable, simplify and accelerate reporting of substandard and falsified medical products by health care professionals to regulatory authorities, was piloted in the Indonesia and the United Republic of Tanzania. The results showed that objectives can only be achieved if the fundamental barriers to reporting are removed. To change the current status quo in respect of underreporting, reporting systems and processes must be designed and implemented with the "reporter" in mind, taking into consideration the motivations for and barriers to reporting – but balancing them with integrated regulatory processes.

23. There are two key limitations to this prescriptive product-focused strategy: (i) lessons learned from the pilot can inform best practices and technical requirements, but each country has a different context, needs and limitations; (ii) a single/global supplier to develop, update and service the application would decrease ownership and adaptability, and may have higher cost implications for scale-up.

[1] WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO (accessed 7 September 2020).

[2] Post-market surveillance of in vitro diagnostics. Geneva: World Health Organization; 2015 (accessed on 6 October 2020).

24. As such, the ISF team has proposed a paradigm shift towards an integrated process-focused strategy. This involves designing a technology-agnostic and normative "playbook" containing practical information on how to develop, implement and sustain a similar project. Member States would then implement the playbook in the light of their local specifications and requirements. Financial sustainability needs to be ensured from the project's inception.

25. The goal remains to increase and improve reporting of substandard and falsified medical products by healthcare professionals to relevant regulatory authorities and on to the WHO Global Surveillance and Monitoring System.

Budget

26. At the first meeting of the Member State mechanism, it was agreed that the mechanism would be funded out of the WHO programme budget. However, it was also recognized that additional resources would have to be mobilized to support the mechanism's work, including Secretariat support.[1] The functions of the Steering Committee include facilitating resource mobilization and budgetary monitoring. The Secretariat has helped mobilize adequate funding from different sources for different areas of the workplan, and is grateful for the support received to date from Member States. It currently receives funding from three main sources: these funds are used to cover implementation of activities and some staff costs, and thereby ensure progress on the mechanism's workplan.

– *The Secretariat seeks the guidance and support of the Member State mechanism with a view to ensuring the financial and operational sustainability of the workplan's implementation.*

ACTION BY THE MEMBER STATE MECHANISM

27. The Member State mechanism is invited to note this update.

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[1] See document A/MSM/1/4.