NINTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS
Provisional agenda item 4C

A/MSM/9/3
8 October 2020

Update by the Secretariat on Activity C

1. The Member State mechanism on substandard and falsified medical products at its eighth meeting in 2019 agreed a list of prioritized activities to implement the mechanism's workplan for the period 2020–2021.[1] Activity C of that list aims to improve Member States' understanding of detection technologies, methodologies and "track and trace" models. It is led by the Secretariat and includes two actions, the second of which is to convene a working group to continue to develop the policy paper on "track and trace" and submit a finalized document[2] to the Member State mechanism.

2. In 2019, a traceability working group was convened composed of members from 19 Member States: seven from the African Region (Benin, Ethiopia, Kenya, Liberia, Mozambique, Nigeria, United Republic of Tanzania); three from the European Region (Russian Federation, Spain, Ukraine); one from the Eastern Mediterranean Region (Iraq); five from the Region of the Americas (Argentina, Brazil, Chile, Mexico, United States of America); two from the South-East Asian Region (India, Indonesia); and one from the Western Pacific Region (Republic of Korea). The traceability working group members proceeded to develop a policy paper on traceability with the input of a consultant contracted by the Secretariat.

3. A first draft of the policy paper was published for public comment on 3 February 2020. Almost 300 comments were received from a variety of stakeholders, including representatives of regulatory agencies, nongovernmental organizations and industry. The Secretariat reviewed and made a preliminary technical assessment of those comments. The working draft of the policy paper was duly amended to include the accepted comments. A glossary was subsequently developed in consultation with the International Coalition of Medicines Regulatory Authorities and was also integrated into the policy paper.

4. The policy paper outlines the features of existing traceability systems and provides guidance on developing workable traceability regulation. In the light of the widely varying needs, capacity and resources of Member States, the risk mitigation and sustainability strategies embedded in implementation efforts will vary. Given the range of possible implementation pathways, a set of guiding principles will assist Member States in establishing systems best suited to their needs and constraints.

5. For this purpose, Member States are encouraged to:

- Establish a suitable governance process for their traceability system based on the analysis of national specificities (e.g. regulatory environment, supply chain management), taking into account the impact of different forms of governance on interoperability, cost, security, regulatory control and access to safe, quality health products;

[1] Document A/MSM/8/4.

[2] See https://www.who.int/publications/m/item/policy-paper-on-traceability-of-medical-products (accessed 22 October 2020).

- Include a costing analysis as well as a sustainability mechanism in their traceability system planning to prevent costs from negatively impacting patients, government, supply chain stakeholders, and ultimately access to health products; and

- Use global standards for product identification, production identification, automatic identification, and data capture and data exchange to reduce set-up and operating system costs and maximize national and international interoperability.

6. Traceability systems implemented by Member States have nine common features, namely identification, use of global standards, lot/batch-level traceability, unit-level serialization, aggregation data, verification, full track and trace vs. point of dispense verification, patient verification, and detection and response, including reporting. Some of the features are mutually exclusive, while others are not. It should be noted that implementation of these features largely depends on the maturity of the existing regulatory system, national resources and the local context of the implementing Member State. Member States are encouraged to assess the potential feasibility of each of these features, including implementation and sustainability opportunities and risks.

7. In terms of implementation, there are various elements that Member States can consider when developing regulation, including the adoption of strategies that focus on risk–benefit analysis, governance and funding, standards, current state analysis, draft regulatory requirements, piloting systems and processes, deadlines, exemptions, exceptions and waivers, enforcement planning, publication and communications planning.

8. The policy paper includes three annexes: (i) Annex 1 outlines the current traceability systems for medical devices;[1] (ii) Annex 2 lists the different global standards organizations; and (iii) Annex 3 describes country and regional experiences in implementing traceability systems.

ACTION BY THE MEMBER STATE MECHANISM

9. The Member State mechanism is invited to consider whether Annex 3 should become a stand-alone document in order that it can be updated more regularly.

10. The Member State mechanism is invited to note this report.

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[1] It should be noted that in vitro diagnostics fall within the scope of the Member State mechanism.