World Health Organization

TWELFTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS
Provisional agenda item 7

A/MSM/12/8
26 October 2023

Governance matters

Possible engagement with non-State actors in the work of the Member State mechanism

Report by the Secretariat

1. During a meeting of the Steering Committee of the Member State mechanism in March 2023, the Secretariat was requested to provide information regarding the possible participation of non-State actors as observers in respect of the work of the mechanism. In response to this request, the Secretariat submitted an earlier version of this report for the consideration of the Steering Committee at its meeting in June 2023. During that meeting, Steering Committee members discussed the merit of involving non-State actors in the work of the mechanism, while emphasizing that the mechanism's primary focus should remain public health. It was agreed that the matter should be brought to the plenary meeting in November 2023 for discussion.

BACKGROUND

2. The participation of stakeholders in the mechanism has been carefully considered by Member States, recognizing that the mechanism was established as an alternative to the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). The Taskforce was the main conduit for WHO's work on substandard and falsified medical products from approximately 2007 to 2009, until Member States raised concerns over the participation in the Taskforce of stakeholders reflecting a broad spectrum of interests, which was felt to have blurred the focus on public health in favour of commercial interests.[1]

3. In response to concerns raised, the Secretariat re-established its programme on what was then referred to as "substandard/spurious/falsely-labelled/falsified/counterfeit medical products," providing a clear distinction between the Secretariat's activities and those of the Taskforce. In addition, the Health Assembly, through decision WHA63(10) (2010), decided to establish a working group on substandard/ spurious/falsely-labelled/falsified/counterfeit medical products.

4. Following the second formal meeting of the Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products, a report by the Working Group, containing a draft resolution, was considered by the Executive Board at its 130th session.[2] The Board, through resolution EB130.R13 (2012), then recommended to the Sixty-fifth World Health Assembly the adoption of a resolution. In May 2012, the Health Assembly adopted resolution WHA65.19, in which, inter alia, it decided to establish "a new Member State mechanism for

[1] See document A/SSFFC/WG/3 Rev.1, as well as document WHA61/2008/REC/3 summary record of the tenth meeting of Committee A, and document EB124/2009/REC/2, summary record of the ninth meeting.

[2] Document EB130/22, Annex.

international collaboration among Member States, from a public health perspective, excluding trade and intellectual property considerations." The name of the mechanism reflected the intention to focus on collaboration among Member States; stakeholders would be invited to participate on specific topics and on an exceptional basis.

CURRENT STATUS

5. According to the terms of reference of the mechanism, which were annexed to resolution WHA65.19,[1] the mechanism "will be open to all Member States[2]". It is further stated that, with respect to relations with other stakeholders and experts, the mechanism "should seek expert advice on specific topics, following standard WHO procedures for expert groups" and that it "will invite other stakeholders to collaborate and consult with the group on specific topics."

6. At its first meeting, the mechanism considered a report by the Secretariat,[3] in which further interpretation of the provisions under resolution WHA65.19 was offered:

> "the mechanism may invite other stakeholders to collaborate and consult 'on specific topics'. Such consultation and collaboration can take place both during and outside the meetings of the mechanism. With regard to consulting stakeholders during the session, the resolution does not envisage permanently opening the sessions of the Member State mechanism to the normal range of participants attending governing bodies (with the exception of regional economic integration organizations where appropriate). It will extend specific invitations to one or more of its sessions to the particular stakeholders that should be consulted or asked to provide input with regard to the discussion of specific topics. The general reference to 'stakeholders', moreover, suggests (in the view of the Secretariat) that such stakeholders do not necessarily have to be among those organizations already entitled to participate in WHO's governing bodies. With regard to consultations and collaboration outside the framework of the formal meetings of the mechanism, various possibilities can be envisaged. These might include inviting relevant stakeholders to meetings of subsidiary working groups or to consultative meetings organized by the Secretariat, or their participation in expert advisory meetings in order to obtain a broad range of views and experiences on particular topics. These channels of consultation and collaboration would take place without prejudice to existing collaboration or joint work with WHO on issues concerning medical products."

7. In the report of its first meeting,[4] the mechanism further clarified its structure, governance and participation, noting that, "the Member State mechanism will invite other stakeholders to collaborate and consult with the group on specific topics on a case-by-case basis".

8. Since then, the WHO Evaluation Office in its 2017 review of the mechanism,[5] noted that "[s]trategically, the mechanism should place greater emphasis on expanding its stakeholder base, involving Member States more actively as well as regulatory agencies and non-State actors, and consolidate its activities, products, processes and outreach to provide sustainable support to Member States." Further, the review includes the following recommendation: "Encourage the engagement of

[1] See document WHA65/2012/REC/1.

[2] And, where applicable, regional economic integration organizations.

[3] Document A/MSM/1/3.

[4] Document A/MSM/1/4, Annex 1.

[5] Document A70/23 Add.1.

additional actors in the mechanism, including academia, manufacturers, nongovernmental organizations, civil society and related technical institutions at global, regional and country levels."

9. For ease of reference, the Table below sets out the current provisions for stakeholder engagement in the Member State mechanism.

Table. Summary of current provisions for stakeholder engagement in the Member State mechanism

Type of engagement open to non-State actors	Is this type of engagement currently provided for in the mechanism's governance structure?	The means by which engagement is enabled
Attendance at meetings of the **mechanism** to consult on specific topics	Yes	Upon invitation from the Chair of the mechanism and if no objection to proposal at the start of each meeting.
Attendance at meetings of the **Steering Committee** to consult on specific topics	Yes	Upon invitation from the Chair of the mechanism and if no objection to proposal at the start of each meeting.
Attendance at meetings of the **Working Group** to consult on specific topics	Yes	Upon invitation from the respective Working Group Chair and if no objection to proposal at the start of each meeting.
Standing invitation to observe m**echanism** meetings	No	By decision of the Health Assembly
Standing invitation to observe **Steering Committee** meetings	No	By decision of the Health Assembly
Standing invitation to observe **Working Group** meetings	No	By decision of the Health Assembly

ACTION BY THE MEMBER STATE MECHANISM

10. The mechanism is invited to note this report. Bearing in mind the current status outlined above, it may also wish to consider the following guiding questions:

- are there opportunities for engaging with non-State actors that should be explored by the mechanism in implementing its workplan?

- are there any particular non-State actors that should be invited to consult on specific topics at particular future meetings of the mechanism?

= = =