

Governance matters

Decision-making of the Member State mechanism

1. At the meeting of the Steering Committee of the Member State mechanism on substandard and falsified medical products in March 2023, the Secretariat explained that, at present, there is no standing arrangement for the mechanism to make intersessional decisions.
2. In the light of Steering Committee interest in the mechanism enhancing its ability to react more agilely to emergent issues, the Secretariat prepared a paper for discussion at the meeting of the Steering Committee in June 2023. The paper explained the steps that would be necessary to facilitate intersessional decision-making through the use of a written silence procedure when necessitated by circumstances to be further clarified.
3. At the June 2023 meeting, Steering Committee members, while recognizing that a written silence procedure might rarely be needed, expressed support for its consideration by the mechanism at its twelfth plenary meeting in November 2023. As with all other mechanism activities, the use of a written silence procedure would be subject to reporting to the Health Assembly.

BACKGROUND

4. The mechanism generally meets only once per year – in plenary session. At that session, it undertakes all necessary decisions and delegates tasks to the Steering Committee to further the mechanism's work between sessions. To enable the mechanism to react more agilely to emergent issues between scheduled sessions, consideration could be given to whether a written silence procedure to permit intersessional decision-making under certain circumstances is warranted.
5. The mechanism has used a written silence procedure once before. At the tenth meeting of the mechanism in October 2021, Member States agreed on the draft list of prioritized activities and actions to implement the workplan of the Member State mechanism for the period 2022–2023,¹ while noting that working groups would be tasked with proposing additional actions to further their work.² Proposals for additional actions were to be submitted to the Steering Committee, which would make a recommendation thereon, for approval by the mechanism through a written silence procedure.

¹ Document A/MSM/10/6.

² See document A/MSM/10/11 Rev.1.

6. While recognizing that the conduct of mechanism business ought to conform as far as practicable with that of the Health Assembly, Member States might conclude that the use of a written silence procedure would be appropriate in exigent circumstances specific to the mechanism's operation; for example, when the Steering Committee assessed that a decision were required before the next mechanism plenary session in order to effectively address an emergent issue concerning substandard and falsified medical products. A written silence procedure would be used as a last resort for matters that could not be dealt with by existing mechanisms, including the work of working groups or already existing mandates. In such instances, provided that the proposal were suitable for adoption without further discussion by the mechanism, the mechanism secretariat would, at the request of the mechanism Chair and based on the Steering Committee's recommendations, communicate the proposed decision to Member States for their consideration by a specified date through a written silence procedure. In the case of an objection, the matter would be discussed at the next meeting of the mechanism.

7. In order to facilitate discussions, the draft written silence procedure that is included as an annex to the present document was provided to the Steering Committee.

ACTION BY THE MEMBER STATE MECHANISM

8. The mechanism is invited to note the report. In its discussions, it is further invited to provide comments and guidance in respect of the following questions:

- in the light of the other steps being considered by the mechanism to permit more agile intersessional action, such as the creation of a working group to address emerging issues, is the introduction of a written silence procedure necessary?
- if there is interest in introducing a written silence procedure, and recognizing that it should only be used as a last resort, what exigent circumstances specific to the mechanism's operation might necessitate its use?
- recognizing that a written silence procedure should not be used for the conduct of regular business, are there any criteria other than those included in the annex to the present document that should be applied to its use?

ANNEX

DRAFT WRITTEN SILENCE PROCEDURE

1. The following written silence procedure will apply in respect of a proposal that the Steering Committee recommends for intersessional adoption by the Member State mechanism (the “mechanism”) based on its assessment that:
 - (a) a decision is required before the next mechanism plenary session in order to effectively address an emergent issue concerning substandard and falsified medical products;
 - (b) the matter cannot be dealt with by existing mechanisms, including the work of working groups or already existing mandates; and
 - (c) the proposal is suitable for adoption without further discussion by the mechanism.
2. At the request of the mechanism Chair, the mechanism secretariat will transmit to Member States such a proposal for consideration under this written silence procedure.
3. The communication will contain the text of the proposal to be considered under this written silence procedure and will set a date for the receipt of any objection. Any such objection is to be conveyed in writing and addressed to the mechanism secretariat. The date for receipt of any objection will be [14] days from the date of dispatch of the communication.
4. In absence of the receipt by the set date of any written objection(s) from Member State(s), the proposal concerned will be considered as having been validly adopted by the mechanism. The adopted proposal will be referred to the mechanism at its next plenary session for information only.
5. In the event of the receipt by the set date of one or more written objections from Member State(s), the proposal concerned will be considered as having not been adopted by the mechanism. The proposal concerned will be referred to the mechanism for consideration at its next plenary session.
6. The mechanism secretariat will communicate the outcome of the written silence procedure to all Member States as soon as possible after the set date referred to in paragraph 3. In the case of a proposal that is adopted pursuant to the written silence procedure, the date of the mechanism secretariat’s communication to that effect will be the date of adoption of the proposal.

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