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# **Options for the structure and governance of the Member State mechanism on substandard/spurious/ falsely-labelled/falsified/counterfeit medical products**

## **Report by the Secretariat**

### **INTRODUCTION**

1. Following the establishment by the Sixty-fifth World Health Assembly of the Member State Mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products,<sup>1</sup> a preparatory meeting open to all Member States was held on 3 July 2012 at WHO headquarters to discuss a number of issues relating to the Member State mechanism and to facilitate preparations for its first meeting. Member States requested the Secretariat to prepare, inter alia, an options paper setting out some possible alternatives for the structure and governance of the new mechanism. Accordingly, this report provides options for the structure, functioning, method of work and long-term financing of the Member State mechanism, drawing when relevant on WHO's experience with other intergovernmental bodies and meetings.

2. The Member State mechanism was established by the Health Assembly as a "committee or subdivision" under the terms of Rule 40 of the Rules of Procedure of the World Health Assembly. The considerations and proposals contained in this report are based on the legal nature of the mechanism as a subsidiary body of the Health Assembly, subject as such to its overall authority. The Health Assembly defined the terms of reference of the mechanism as well as the essential aspects of its structure, methods of work and relations with other stakeholders.<sup>2</sup> It also set a schedule of reporting and decided on a review after three years of operation. The present report builds on the decisions already taken by the Health Assembly and the preparatory meeting of Member States held on 3 July 2012, and presents a number of more detailed proposals on implementation.

### **TERMS OF REFERENCE OF THE MEMBER STATE MECHANISM**

3. The terms of reference of the mechanism are presented as objectives within the context of its general goal of promoting the prevention and control of substandard/spurious/falsely-labelled/falsified/counterfeit medical products as a means of protecting public health and promoting access to affordable, safe, efficacious and quality medical products. The terms of objectives (1),(2),(7)

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<sup>1</sup> Resolution WHA65.19.

<sup>2</sup> See resolution WHA65.19, Annex.

and (8) of the mechanism include, among others, the identification of major needs and challenges in the context of substandard/spurious/falsely-labelled/falsified/counterfeit medical products, the facilitation of consultation and cooperation and the strengthening of national and regional capacities. The terms of objective (6) require the Member State mechanism to collaborate with and contribute to the work of other areas of WHO that address access to medical products including the supply and use of generic medical products. It is therefore clear that the intention of the Health Assembly is that the mechanism should complement ongoing work on medical products based on previous Health Assembly resolutions in order to ensure synergy with the specific focus of the mechanism on SSFFC medical products and to avoid duplication of effort and cost.

4. The terms of reference of the Member State mechanism have also to be understood in the light of its nature as a subsidiary body of the Health Assembly, to which it has to report its conclusions and recommendations for further consideration.

## **BUREAU OF THE MEMBER STATE MECHANISM**

5. At the preparatory meeting of Member States it was decided that the interim bureau for the first meeting of the Member State mechanism will consist of the six regional coordinators, or other delegates appointed by the regional groups. The interim bureau will aim to reach agreement on a bureau composed of a chairperson and six vice-chairpersons to be formally considered by the first meeting of the Member State mechanism. Other arrangements for the final bureau composition may still be considered.<sup>1</sup>

6. Precedents from previous intergovernmental bodies and meetings may help to guide a final decision on the most appropriate structure for the bureau of the Member State mechanism. For instance, the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property was composed of one chairman and five vice-chairmen.<sup>2</sup> The Intergovernmental Negotiating Body for the WHO Framework Convention on Tobacco Control was composed of one chairperson and six vice-chairpersons,<sup>3</sup> whereas the Open-Ended Working Group of Member States on Pandemic Influenza Preparedness had two co-chairpersons who were supported by six vice-chairpersons.<sup>4</sup>

7. On balance, and taking into account the decision taken at the preparatory meeting, Member States may wish to consider electing one chairperson and six vice-chairpersons as the most balanced option for the structure of the bureau in order to facilitate a regular rotation of the chairmanship on a regional basis.

8. Member States may also wish to consider an appropriate duration for the term of office of the chairperson and vice-chairpersons, given that the Health Assembly did not set an end-date for the work of the mechanism as it did for the work of previous intergovernmental meetings and bodies. In those cases, the persons elected as officers remain in that position until the end of the mandate of the body concerned, whereas the officers of sessional bodies such as the Health Assembly, Executive Board and Regional Committees are elected until the subsequent regular session of the organ

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<sup>1</sup> Preparatory meeting on the first meeting of the Member State Mechanism on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products: Summary by the Chair.

<sup>2</sup> See document A/PHI/IGWG/1/6, Annex 1.

<sup>3</sup> See document A/FCTC/INB1/SR1.

<sup>4</sup> See document A/PIP/OEWG/2, paragraph 1.

concerned. In order to balance regional rotation with ensuring continuity, Member States may wish to consider electing the officers for a term beginning at the end of a regular session of the mechanism and ending at the end of the next regular session. This would ensure that the same officers follow the work performed between sessions of the mechanism and preside over the session that considers the outcome of such work.

## **METHOD OF WORK DURING THE SESSIONS OF THE MECHANISM**

9. Member States may consider the following options when considering methods of work during the sessions of the mechanism.

**Option 1:** Member States can choose to organize work only through plenary meetings.

**Option 2:** Member States may consider organizing the work by dividing the agenda among working groups or similar subdivisions that subsequently report to a plenary meeting. This could be done on an ad hoc basis depending on the agenda and workload of a particular session or on a standing basis. In the latter case, standing working groups could be allocated different issues or tasks relating to the nature of the topics on the agenda of a particular session. Each of the working groups would report on its deliberations to the plenary meeting for further consideration, adoption or other action.

## **RULES OF PROCEDURE**

10. The Rules of Procedure of the Health Assembly apply to the mechanism as a subsidiary body of the Assembly established under Rule 40 of its Rules of Procedure. At the same time, Rules 83 and 84 ensure flexibility in adapting the Rules to the particular functions and needs of a subsidiary body. Rules 83 and 84 provide that, subject to any decision of the Health Assembly, committees and sub-committees to the Health Assembly shall conform as far as practicable to the Rules relative to the conduct of business and voting in the plenary meetings; and that the chairman of each sub-committee shall apply the Rules applicable to committees in so far as he considers it advisable with a view to expediting the dispatch of business. Recent precedents of other intergovernmental bodies and meetings confirm the use by Member States of the flexibilities inherent in the Rules of Procedure of the Health Assembly, e.g. with reference to the establishment of a bureau, organization of a method of work, or participation by other stakeholders in meetings.

## **SUBSIDIARY WORKING GROUPS**

11. In resolution WHA65.19 the Health Assembly decided that the Member State mechanism may establish subsidiary working groups from among its members to consider and make recommendations on specific issues.<sup>1</sup> While the establishment of subsidiary bodies during the sessions of the mechanism has been dealt with above, the long-term nature and the broad scope of the terms of reference of the mechanism may lead the Member State mechanism to establish working groups of Member States (and, where applicable, regional economic integration organizations) as a tool to carry out intersessional work. The Rules of Procedure of the Health Assembly would apply equally to subsidiary working groups, providing the necessary flexibility to respond to the particular requirements of the group in question. Such subsidiary working groups could be established on an

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<sup>1</sup> See resolution WHA65.19, Annex, paragraph 2 under “Structure”.

ad hoc basis or, if there is a need for a longer-term consideration of specific issues (e.g. further work on the definition of substandard/spurious/falsely-labelled/falsified/counterfeit medical products), the Member State mechanism might consider the establishment of a standing subsidiary working group that would meet regularly between sessions. In both cases, the subsidiary working groups would report their conclusions and recommendations to the main session of the Member State mechanism.

12. The convenience of establishing subsidiary working groups of Member States in order to advance the work programme of the mechanism should be balanced against the financial, practical and logistical implications of holding such meetings, the associated requirements for Secretariat support, as well as the need for preparatory activities. Depending on the particular topic to be dealt with, Member States should carefully consider the usefulness of an intergovernmental working group or, alternatively, entrust technical work to the Secretariat, to stakeholders collaborating with the mechanism in accordance with resolution WHA65.19, or to expert advisory groups that can be convened by the Secretariat. An appropriate combination of these alternative mechanisms may better contribute to a technically sound and cost-effective advancement of the objectives of the Member State mechanism.

13. The practice adopted by the Conference of the Parties to the WHO Framework Convention on Tobacco Control may serve as a useful precedent in cases where the Member States mechanism considers it necessary to establish a subsidiary working group of Member States. The working groups that are mandated to develop guidelines on the implementation of specific Articles of the FCTC have key facilitators appointed by the Conference of the Parties, i.e., Parties to the Convention who volunteer to take the lead in supporting the work of the group,<sup>1</sup> either through resource mobilization or technical work,<sup>2</sup> as well as Parties who offer to partner in the development of the guidelines and others who act as reviewers.<sup>3</sup> Relevant stakeholders with specific expertise in the subject matter of the guidelines are invited to actively participate and contribute to the elaboration of the guidelines as requested by the Secretariat. This method of work has promoted resource mobilization, efficiency as well as engagement by Parties in a position to contribute to a specific item of work. Particular attention has been given to ensure adequate regional representation in the working groups.

## **PARTICIPATION**

14. Pursuant to resolution WHA65.19 the Member State mechanism will be open to all Member States – and, where applicable, regional economic integration organizations – and should include participants with expertise in national health and medical products regulatory matters. Regional groups will provide input as appropriate.

15. The provisions of resolution WHA65.19 also indicate that Member States will invite other stakeholders to collaborate and consult with the group on specific topics. The issue of participation by entities other than Member States in WHO intergovernmental meetings has been dealt with by the Health Assembly and the Board largely in two alternative manners.

- (a) In some cases (e.g. the Intergovernmental Negotiating Body of the WHO Framework Convention on Tobacco Control and the Intergovernmental Working Group on the Global

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<sup>1</sup> See, for example, document A/FCTC/COP/2/7, paragraph 5.

<sup>2</sup> See, for example, document A/FCTC/COP/1/DIV/8, p. 48.

<sup>3</sup> See, for example, document A/FCTC/COP/1/DIV/8, p. 48.

Strategy and Plan of Action on Public Health, Innovation and Intellectual Property) the Director-General has been requested, in the resolutions convening those meetings, to invite the range of participants that attend governing bodies meetings. In those cases, the meetings are by default open to such participants unless the organ concerned decides to hold closed meetings in accordance with the applicable Rules of Procedure.

(b) In other cases (e.g. the Open-Ended Working Group of Member States on Pandemic Influenza Preparedness and the Working Group of Member States on SSFFC medical products), the relevant resolutions are silent as to participation beyond Member States and, where applicable, regional economic integration organizations. In those cases, the meetings were by default not open to other participants unless the organs concerned decided to invite certain entities, e.g. nongovernmental organizations, with a view to securing their technical input or to consulting with them on certain items of their agendas. In the case of the Open-Ended Working Group of Member States on Pandemic Influenza Preparedness, an invitation was extended to a stakeholder that did not otherwise already enjoy a standing invitation to governing bodies meeting – namely, the Developing Country Vaccine Manufacturers Network.

16. The relevant provision in resolution WHA65.19 follows the second approach, as 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.

17. 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.

## **EXPERT INPUT**

18. The Annex to resolution WHA65.19 provides that the Member State mechanism “should seek advice on specific topics, following standard WHO procedures for expert groups”. The broad scope of the terms of reference of the mechanism, and the complex technical nature of some of the issues falling therein, may indeed require specialized technical advice to facilitate the deliberations of the mechanism.

19. In view of the clear requirement that the mechanism utilize existing WHO procedures, it is proposed that the Secretariat, at the request of the Member State mechanism, convene expert advisory meetings in accordance with the applicable WHO Regulations or otherwise seek the views and input of individual experts in relevant fields in accordance with normal WHO procedures. The findings and conclusions of those meetings would then be reported to the mechanism by the Director-General.

20. This possibility would not prevent the mechanism from requesting the Director-General to invite experts to attend the sessions of the mechanism in order to interact directly with it and provide their views and advice, or from consulting and collaborating with relevant stakeholders as provided for in the terms of reference of the mechanism.

21. In cases when individual experts are consulted or invited to participate in meetings to support the work of the mechanism, the Secretariat will apply WHO's policy and practices concerning disclosure of possible conflicts of interest. Any relevant interest so disclosed, and appropriate remedial measures, will be summarized in the report of the meetings concerned or will be otherwise reported in an appropriate manner to the Member State mechanism.

## **REPORTING**

22. Resolution WHA65.19 provides that the Member State mechanism shall be reviewed by the Health Assembly after three years of its operation. The resolution also specifies that the mechanism should submit a report to the Health Assembly through the Executive Board on progress and provide annual recommendations for the first three years and every two years thereafter. The format of those reports should probably best be considered after the programme of work of the mechanism, and thus after the scope of its reporting requirements has been agreed upon. It can be anticipated that subsidiary working groups established by the Member State mechanism, as well as expert advisory groups and other mechanisms to support its work, will be required to make reports to the Member State mechanism. The format and frequency of such reports should be also assessed, taking also into account the financial implications of such reporting.

## **CONCLUSION**

23. Member States are invited to consider the above mentioned options and proposals with a view to deciding the most appropriate arrangements for the work of the mechanism.

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