
Governance

Report by the Secretariat

1. The Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products (hereinafter the mechanism), at its first meeting in November 2012, took a number of decisions concerning the governance of the mechanism. It decided, in particular, that the mechanism will have a Chairperson as well as two Vice-Chairpersons for each region. The officers will constitute the steering committee of the mechanism; their term of office will start at the end of a regular session of the mechanism and it will be of three years for the officers appointed after the first meeting, whereas subsequent terms of office will expire at the end of every second regular session. The mechanism also established an ad hoc process to lead to the appointment of the officers and the establishment of the first Steering Committee since this could not be accomplished during the first meeting.

2. The Secretariat would like to bring to the attention of the mechanism a number of issues that either arose out of the implementation of the decisions taken at the first meeting, or were not addressed at that meeting. A decision on these issues would facilitate the work of the mechanism and the Steering Committee from a governance and procedural perspective.

CHAIRPERSON OF THE MECHANISM

3. To date, it has not been possible to appoint a Chairperson of the mechanism owing to a lack of consensus. In view of the consequences of this situation for the work of the mechanism, the Sixty-sixth World Health Assembly recommended that the chairmanship of the Steering Committee operate on the basis of rotation, on an interim basis, without prejudice to the existing terms of reference for the mechanism.¹ Pursuant to that decision, it was agreed that a Vice-Chairperson from the African Region would serve as first rotating Chairperson; Dr Paul Botwev Orhii (Nigeria) was selected for that post and chaired the meeting of the Steering Committee in July 2013.

4. If the mechanism wishes to continue for the moment with the system of rotating chairmanship recommended by the Health Assembly, it may wish to consider two issues that would facilitate a smoother implementation of that system and take decisions thereon.

- **The pattern of rotation among regions, or a mechanism to choose the region selected to provide the Chairperson.** A simple solution would be to rotate the chairmanship following the alphabetical order of the regions, especially since the region already selected is also the

¹ See decision WHA66(10).

first in alphabetical order and that order could simply continue to be followed. Alternatively, the regional coordinators – who have already been informally facilitating certain aspects of the functioning of the mechanism – could be given the task of agreeing on a case-by-case basis on the next region to provide the rotating Chairperson. It should be clearly understood that the region providing the rotating Chairperson would have only one Vice-Chairperson during that period.

- **The length of the term of office of the rotating chairperson.** This should be clarified so as to avoid doubts about the authority of the Chairperson and the legitimacy of actions taken by him or her in the context of the work of the mechanism and the Steering Committee. A possible approach would be to have the rotating chairperson serve from the closure of a regular session of the mechanism to the closure of the subsequent regular session. This would ensure some continuity and accountability in connection with the cycle of the governance of the mechanism and of specific work products that would be submitted to the mechanism for approval. Alternatively, the term of office could be linked to other identifiable events in the work cycle of the mechanism – for example, meetings of the Steering Committee. It would not seem advisable to envisage a rigidly timed rotation. If, for example, the position of Vice-Chairperson rotated every six months, this would risk a change in the presiding officer taking place in the middle of a particular work stream.

LEGAL STATUS OF THE VICE-CHAIRPERSONS

5. There has been uncertainty over whether the Vice-Chairpersons serve in their personal capacity or as representatives of their respective Member States. The decisions taken at the first meeting of the mechanism do not clarify this point. It is uncontested, in any case, that the Chairman is appointed in his/her personal capacity.

6. Under the Rules of Procedure of the Health Assembly, which are applicable to the mechanism as a subsidiary body thereof, officers are elected in their personal capacity from among the representatives of Member States. At the same time, the flexibility that the Rules of Procedure extend to “subdivisions” of the Health Assembly (Rules 40 and 84) enable them to tailor certain aspects of the Rules of Procedure to their own specific needs and functions. With regard to the legal status of the officers of the mechanism, it should be recalled that the Intergovernmental Negotiating Body that negotiated the WHO Framework Convention for Tobacco Control and the Intergovernmental Working Group that negotiated the revised International Health Regulations (2005), elected their Vice-Chairpersons as representatives of their respective Member States. As a consequence, the replacement of a Vice-Chairperson did not require a new election by the body concerned but fell under the authority of the Member State, subject to a notification to the Director-General for the information of Member States.

7. While the latter approach has been used exceptionally in a few cases and represents a departure from the principle that officers serve in their personal capacity, it may serve a useful purpose in case of subsidiary bodies established for a potentially long period of time and performing tasks that require regular meetings of their officers as a bureau or steering committee. In particular, it avoids the predicament of having to wait until the subsequent plenary meeting of the body in question in order to elect a new Vice-Chairperson and thus reduces the risk of unfilled positions within the groups of appointed officers.

8. In view of the foregoing, the mechanism may want to consider clarifying formally that Vice-Chairpersons will serve as representatives of their respective Member States. In that case, as

noted above, a Vice-Chairperson who has to relinquish his/her post may be replaced by the Member State concerned instead of requiring a new election at the subsequent meeting of the mechanism. Moreover, if the Vice-chairperson is unable to attend a particular meeting, the Member State can appoint another representative to act on behalf of the Vice-Chairperson. It is recommended, however, that the Member State formally notify the Steering Committee through the Secretariat of any such change.

PARTICIPATION AT THE MEETINGS OF THE STEERING COMMITTEE

9. The decisions taken at the first meeting of the mechanism are silent as to whether meetings of the Steering Committee may be attended by other participants besides the officers of the mechanism.

10. The Steering Committee, at its meeting in July 2013, provisionally accepted that representatives from those Member States whose nationals were already present on the Committee by virtue of their position as officers of the mechanism could attend the meeting for the purpose of consultation and advice. It was felt that discussion on complex agenda items, such as on the work plan of the mechanism in the case of the aforementioned meeting of the Steering Committee, warranted the presence of persons with a technical or managerial expertise to support the work of the Vice-Chairpersons. The participation of observers from other Member States, however, was not supported and it was also made clear that membership in the Steering Committee was limited to the persons formally appointed in accordance with the procedure of the mechanism.

11. The mechanism may want to consider endorsing that arrangement as the future mode of operation of the Steering Committee in terms of participation in its meetings.

ACTION BY THE MECHANISM

12. The mechanism is invited to consider the issues raised above and to approve the proposals formulated by the Secretariat, or to provide guidance to the Secretariat if a further elaboration of those or other governance questions is required.

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