
Substandard/spurious/falsely-labelled/ falsified/counterfeit medical products

Report by the Secretariat

1. The Sixty-fifth World Health Assembly adopted resolution WHA65.19 establishing a Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products.¹
2. The first meeting of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products took place in Buenos Aires, from 19 to 21 November 2012, and was attended by 65 Member States and one regional economic integration organization. A report of that meeting, which was also considered by the Executive Board at its 132nd session,² is attached in the Annex.
3. With respect to the election of the officers of the mechanism following the first meeting, the first meeting of the mechanism decided that regional groups would agree among themselves on a Chairperson and submit to the Secretariat the names of two Vice-Chairpersons per region; those officers would form the Steering Committee.³ All regions have responded and the names of the Vice-Chairpersons have been submitted. Member States have not yet agreed on a Chairperson for the mechanism and discussions are ongoing, therefore a formal meeting of the Steering Committee has not yet taken place.
4. In an effort to move forward, the Regional Coordinators requested that the Secretariat organize an informal meeting of the Steering Committee, which took place in Geneva on 11 April 2013. It was attended by the Vice-Chairpersons or their nominated replacements, and chaired by the Secretariat in the absence of a Chairperson.
5. With respect to the Open Ended Working Group to identify the actions, activities and behaviours that result in SSFFC medical products, which was established by the Member State mechanism at its first meeting,⁴ it was agreed at the informal meeting of the Steering Committee that

¹ The goal, objectives and terms of reference of the Member State mechanism were established in the Annex to resolution WHA65.19.

² See document EB132/20.

³ See document EB132/20, Annex, Appendix 1, paragraph 1.

⁴ Document EB132/20, Annex, paragraph 6.

the Open Ended Working Group be convened as soon as possible after the Sixty-sixth World Health Assembly. Several options for finalizing the workplan were discussed. In order to make the most of the presence of the technical experts in Geneva, members of the Steering Committee suggested that it would be useful to hold an informal technical consultation on the workplan on the day following the adjournment of the Open Ended Working Group. Recognizing that the Steering Committee is responsible for feeding suggestions on the remaining elements of the workplan back to the Member State mechanism, there was also a suggestion to hold a Steering Committee meeting on the day after the technical consultation. Preparations to conduct these meetings in Geneva during July 2013 are under way.

6. The Secretariat was requested to identify possible dates for the second meeting of the Member State mechanism. It is anticipated that this meeting will take place in November 2013.

ACTION BY THE HEALTH ASSEMBLY

7. The Health Assembly is requested to note the report.

ANNEX

**REPORT OF THE FIRST MEETING OF THE MEMBER STATE MECHANISM ON
SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT
MEDICAL PRODUCTS**

The first meeting of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products met from 19 to 21 November 2012 in Buenos Aires and was chaired by H.E. Ambassador Umunna Humphrey Orjiako of Nigeria with the following Vice-Chairpersons: Iskari Fute of the United Republic of Tanzania, Colin McIff of the United States of America, Ahsan Nabeel of Pakistan, Roland Driecce of the Netherlands, Hemant Kotalwar of India, and Ruth Lee Choo Ai of Singapore. The session was attended by representatives from 65 Member States and one regional economic integration organization.

The meeting considered three reports prepared by the Secretariat on mapping international organizations that are active in the field of SSFFC;¹ options for the structure and governance of the Member State mechanism² and an overview of the current situation regarding SSFFC medical products.³

With regard to the election of the officers of the mechanism following the closure of the first meeting, it was agreed that regional groups will consult and submit to the Secretariat the names of two vice-chairpersons per region by 15 January 2013. Regional groups will agree among themselves on a chairperson by the same deadline as that given for the vice-chairpersons, that is, 15 January 2013. Until then, the term of office of the current bureau is extended.

Until the steering committee is established, the current bureau will continue to serve on an interim basis.

The meeting discussed the scope of the Member State mechanism, areas of work and workplan, structure and governance, funding, and dates of the next meeting. The decisions taken by the mechanism on these issues are appended to this report (see Appendices 1 and 2).

The meeting decided, as a first activity of the new Member State mechanism, to establish an open-ended working group to identify the actions, activities and behaviours that result in SSFFC medical products, as outlined in resolution WHA65.19, Annex, objective (4). It was estimated that the mandate of the proposed working group could be accomplished within an approximate time frame of between two and six months, depending on the method of work.

Furthermore, the meeting decided that work on those activities identified under areas 1, 2, and 3 of the workplan that were agreed could start immediately (see Appendix 2).

The mechanism requests the steering committee to further discuss the remaining elements of the workplan.

The steering committee will hold its first meeting no later than the period of the Sixty-sixth World Health Assembly.

¹ Document A/MSM/1/2.

² Document A/MSM/1/3.

³ Document A/MSM/INF./1.

Appendix 1

STRUCTURE, GOVERNANCE AND FUNDING OF THE MEMBER STATE MECHANISM

1. The Member State mechanism will have a steering committee composed of the Chairperson, and two vice-chairpersons for each region. Only one vice-chairperson per region, at most, will receive travel support from the budget of the mechanism, in accordance with resolution WHA50.1. The Secretariat will provide any necessary support to the steering committee.
2. The term of office of the chairperson and vice-chairpersons will start at the end of a regular session of the mechanism. The term of the officers appointed after the first meeting will last for three years. Subsequent terms of office will expire at the end of every second regular session.
3. The steering committee will carry out the following functions, to be reviewed by the second meeting of the Member State mechanism:
 - (a) Agree logistical elements of the Member State mechanism meetings including dates and agenda.
 - (b) Provide oversight and prioritization of the implementation of the Member State mechanism workplan.
 - (c) Contribute to operational implementation, drawing on expertise from the Secretariat including administrative and technical work.
 - (d) Facilitate communication between any intersessional working group(s) and Member States at large between meetings of the Member State mechanism.
 - (e) Where there are developments from intersessional work and there is agreement by Member States, the steering committee may communicate such updates to the WHO governing bodies. In cases where there is no agreement, those work elements must be forwarded to the next meeting of the Member State mechanism.
 - (f) Facilitate resource mobilization and budgetary monitoring.
 - (g) Steering committee members should work closely with their region. Regions may define additional processes or guidelines to orient intraregional participation in the work of the steering committee.
 - (h) All intersessional work is open to input from all Member States.¹ The steering committee should inform all Member States¹ of the work proposed and undertaken in each area, to allow for an inclusive and transparent process.

¹ And, where applicable, regional economic integration organizations.

- (i) Policy decisions related to intersessional work and activities must be submitted to and considered by the plenary of the Member State Mechanism.
- (j) Each area of work should have at least one key facilitator.

With regard to the methods of work of the mechanism, policy issues will be discussed in plenary meetings, ad hoc drafting groups will be established during any meeting if the need arises; and working groups could be set up by the mechanism on a case-by-case basis to meet between formal meetings, in order to undertake technical work, taking into account financial implications and the agreed workplan.

As needed, the Member State mechanism will invite other stakeholders to collaborate and consult with the group on specific topics on a case-by-case basis.

As needed, the Member State mechanism should seek expert advice on specific topics, following standard WHO procedures for expert groups.

Any subsidiary group will report to the mechanism. The Chairperson may present the reports of the mechanism to the Health Assembly. In case of issues, other than policy matters, which require the attention of the Health Assembly before the annual session of the mechanism, the steering committee may report directly to the Health Assembly.

The mechanism will be funded from the programme budget of WHO. Additional resources will have to be mobilized to support the work of the mechanism, including Secretariat support, taking into account the need to ensure transparency and to avoid conflicts of interest.

The next regular meeting of the Member State mechanism will be held in Geneva during the last quarter of 2013. The exact dates will be decided by the steering committee.

Appendix 2

WORKPLAN

1. Strengthening and capacity building of national and regional regulatory authorities and quality control laboratories (both national and regional level) (related to Objective 5)

- (a) Identify strengths and weaknesses of national/regional regulatory capacity.
- (b) Identify actions to improve Member State/regional regulatory capacities.
- (c) [Utilize][Disseminate and] Develop [or leverage on] [existing] [and develop new] training programmes for capacity building in countries/regions with identified needs.
- (d) Promote availability of adequate resources for capacity building.

2. Cooperation and collaboration among national (and regional) authorities and exchange of experiences, lessons learnt, best practices and information on ongoing activities at national, regional and global levels (related to Objectives 1, 3)

- (a) Exchange experiences, lessons learnt and information about [authentication and] detection technologies and methodologies.
- (b) [Exchange experiences, lessons learnt and information about Track and Trace technologies and methodologies and models].
- (c) Sharing of experiences, best practices and lessons learnt on cost-effective prevention, [detection] and control [strategies] for SSFFC medical products.

3. Communication, education and awareness raising (related to all Objectives)

- (a) Vigilance and awareness education among consumers, health professionals and industry.
- (b) Advocacy to political leadership.

4. Facilitate consultation, cooperation and collaboration with relevant stakeholders in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective

5. Identify actions, activities and behaviours that result in SSFFC medical products (related to Objective 4)

- (a) Identify the activities and behaviours that result in SSFFC medical products being prevented and controlled due to the health risk they present to the population.
- (b) Identify those activities and behaviours that fall outside the mandate of the mechanism and separate them from the list of activities and behaviours aforementioned.

6. Strengthen national and regional capacities in order to ensure the integrity of the supply chain (related to Objective 1, 2 [and 4])

[[To identify, develop or promote activities and guidelines for the prevention, detection and control related to the supply chain integrity of SSFFC medical products]

- (a) Identify actions and activities for prevention and control of SSFFC medical products.
- (b) Promote [Good Distribution Practices][the control of distribution channels to prevent SSFFC medical products, strengthen] Good Distribution Practices.
- (c) Identify actions and activities to Internet sales [that contribute to SSFFC medical products].
- (d) Produce guidelines for Member States and the WHO action/response plan to prevent and control the activities and behaviours identified under 4, suitable to the scope of the Member State mechanism.
- (e) Develop terms of reference for national/regional dedicated programme officer or office to address SSFFC.
- (f) [Develop [guidelines]/[legal and policy tools] to monitor and enforce unethical promotion of medicines].
- (g) [Organize disclosure of QSE data for medical products].
- (h) Develop detection strategies and action mechanisms [in case of detection] of spurious/falsified/falsely-labelled medical products.
- (i) [Develop new technologies for preventing the distribution of spurious/falsified/falsely-labelled medical products].
- (j) Identify current programmes eventually related to the actions/behaviours to avoid duplication of work [group with D].
- (k) [To urge Member States to have clean and up-to-date directories of legitimate manufacturers and to be willing to reveal the status of any manufacturers upon official request by drug regulatory authorities].
- (l) [A single point of contact should be identified]].

7. Collaboration on surveillance and monitoring (related to Objective 8)

- (a) Development of methodologies, criteria and tools for data collection and analysis.
- (b) Sharing [of information on incidents through single points of contact]/[on incidents (Global Surveillance System, Single Point of Contact)].
- (c) [Increased regional cooperation].

8. Collaboration with and contribution to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products, including but not limited to the supply and use of generic medical products, which should complement measures for the prevention and control of SSFFC medical products (related to Objective 6)

- (a) [[Contribute to the work of other areas of WHO that] Develop measures to facilitate the sale of quality medical products at an affordable price].
- (b) [Create capacity and tools to monitor and control price of medical products].
- (c) [[Contribute to the work of other areas of WHO that] Promote local manufacturing of affordable quality medical products and facilitate transfer of technologies].
- (d) [Create awareness of policies that hinder access to affordable medical products].
- (e) [Promote the prescription of medicines using International Non-Proprietary Names].
- (f) [Review human and financial resource allocation on promotion to access to affordable quality, safe and efficacious medicines.]
- (g) [Address access to quality, safe, efficacious and affordable medical products, including, but not limited to, the supply and use of generic medical products].

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