World Health Organization

FIFTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS
Provisional agenda item 7

A/MSM/5/4
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Review of the Member State mechanism on substandard/spurious/falsely-labelled/ falsified/counterfeit medical products

TERMS OF REFERENCE

1. Following resolution WHA65.19 (2012) and decision WHA68(12) (2015), and the decision of the Steering Committee of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products at its meeting of September 2015, these terms of reference describe the approach to conducting the review of the mechanism. The aim of the review is to estimate the extent to which the mechanism has progressed in achieving its objectives; to identify gaps and remaining challenges; and to make recommendations on the way forward.

Background

2. In 2012, the Sixty-fifth World Health Assembly adopted resolution WHA65.19, in which it decided to establish a Member State mechanism with the general goal of promoting, through effective collaboration among Member States and the Secretariat, the prevention and control of SSFFC medical products and associated activities in order to protect public health and promote access to affordable, safe, efficacious and quality medical products. The mechanism's terms of reference further set out that its functioning would be reviewed after three years of operation. In 2015, the Sixty-eighth World Health Assembly adopted decision WHA68(12), in which it decided to postpone the review of the mechanism by one year.

3. The Steering Committee of the Member State mechanism, at its meeting in September 2015, decided that the review of the mechanism, which will be conducted through an online survey,[1] will examine the success of the mechanism in achieving the objectives set forth in resolution WHA65.19, documenting achievements, gaps and remaining challenges, and that it will make recommendations on the way forward.

4. At the fourth meeting of the Member State mechanism, held on 19 and 20 November 2015, there was agreement that the review process should be led by the WHO Evaluation Office, and that further details on the review, including on the questionnaire, would be provided to the Steering Committee at its meeting in March 2016. Subsequently, the Steering Committee members agreed that, based on decision WHA68(12), the review should cover the period 2012−2016. In this regard, the review will be conducted after the fifth meeting of the Member State mechanism in 2016, following

[1] See document A/MSM/5/4 Add.1 for the survey questionnaire.

which it will be submitted to the Seventieth World Health Assembly in May 2017. In addition, the review will be uploaded on the Mednet collaborative platform, providing Steering Committee members with an opportunity to view it before it is considered by the Health Assembly.

Objectives of the mechanism

5. The Member State mechanism on SSFFC has the following objectives:[1]

(a) to identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies and control of "substandard/ spurious/falsely-labelled/falsified/counterfeit medical products" in order to strengthen national and regional capacities;

(b) to strengthen national and regional capacities in order to ensure the integrity of the supply chain;

(c) to exchange experiences, lessons learnt, best practices, and information on ongoing activities at national, regional and global levels;

(d) to identify actions, activities and behaviours that result in "substandard/spurious/falsely labelled/falsified/counterfeit medical products" and make recommendations, including for improving the quality, safety and efficacy of medical products;

(e) to strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries;

(f) to collaborate with and contribute 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 "substandard/spurious/falsely-labelled/falsified/counterfeit medical products";

(g) to 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;

(h) to promote cooperation and collaboration on surveillance and monitoring of "substandard/spurious/falsely-labelled/falsified/counterfeit medical products"; and

(i) to further develop definitions of "substandard/spurious/falsely-labelled/falsified/ counterfeit medical products" that focus on the protection of public health.

[1] See document WHA65/2012/REC/1, resolution WHA65.19, Annex.

Purpose of the review and high level objectives

6. The overall purpose of the review is as follows: to estimate the extent to which the Member State mechanism has progressed in achieving its objectives in the period 2012–2016; to identify gaps and remaining challenges; and to make recommendations on the way forward.

7. The objective of the review is to respond to the following high-level questions:

- To what extent have the objectives of the mechanism been achieved?
- Which are the major gaps in the achievement of those objectives?
- Which are the principal factors that have either supported or hampered the achievement of the mechanism objectives?
- How could the mechanism be more effective in achieving its objectives?

Approach

8. The review will seek the informed opinion of the primary stakeholders of the mechanism, namely, all Member States (including health ministries and national/regional regulatory agencies), together with Secretariat staff involved in supporting the implementation of the mechanism by Member States, such as the mechanism's secretariat and Regional Advisors for essential medicines and health products. It is also proposed that nongovernmental organizations in official relations with WHO[1] are made aware of the review, and that they may express the wish to participate in it, at which point, the Evaluation Office would provide them access to the online survey.

9. The survey will be managed through secure WHO electronic platforms.

10. The scope of the review would cover the implementation of the eight strategies and action areas defined in the work plan of Member State mechanism,[2] together with their relationship with the achievement of the objectives of the mechanism. The review will estimate the extent of implementation of the work plan and will explore its suitability to achieve the corresponding objectives. The review will also explore the factors that may have favoured or hampered implementation of the work plan; and will collect survey respondents' proposed options for improving the effectiveness of the mechanism.

Steering and oversight

11. The review will be managed by the WHO Evaluation Office.

[1] Following the adoption by the Sixty-ninth World Health Assembly of the Framework of Engagement with Non-State Actors (resolution WHA69.10), the nongovernmental organizations concerned would fall within the group of non-State actors in official relations with WHO.

[2] See document A/MSM/2/6, Annex 2.

Timeline

12. The review will be conducted during the last quarter of 2016 and the first quarter of 2017, with the intention of finalizing it in time for consideration by the Seventieth World Health Assembly in May 2017. The figure below sets out a high-level timeline.

Figure. Timeline for the review of the Member State mechanism on SSFFC medical products

October 2016: Finalization of questionnaire in collaboration with Steering Committee of the mechanism
November 2016: Presentation of terms of reference and questionnaire to the mechanism
December 2016: Launch of survey to canvass views of stakeholders in the mechanism

February 2017: Finalization of data collection and analysis
March 2017: Presentation of preliminary results to Steering Committee
April 2017: Preliminary results posted in MedNet for review by the mechanism
May 2017: Presentation of review report to Seventieth World Health Assembly

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