

## **Review of the Member State mechanism on substandard/spurious/falsey-labelled/ falsified/counterfeit medical products**

1. Further to resolution WHA65.19 (2012) and decision WHA68(12) (2015), a review of the Member State mechanism on substandard/spurious/falsey-labelled/falsified/counterfeit medical products was conducted, covering the period 2012–2016. At the fourth meeting of the Member State mechanism in November 2015, there was agreement that the review process should be led by the WHO Evaluation Office.<sup>1</sup>

2. In line with the terms of reference of the Member State mechanism,<sup>2</sup> the Secretariat is submitting the executive summary of the final review report to the Seventieth World Health Assembly (see Annex).<sup>3</sup>

### **ACTION BY THE HEALTH ASSEMBLY**

3. The Health Assembly is invited to note the report.

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<sup>1</sup> See document A69/41, Annex.

<sup>2</sup> See resolution WHA65.19, Annex (document WHA65/2012/REC/1).

<sup>3</sup> The full report of the review is available on the website of the WHO Evaluation Office, see [http://www.who.int/about/finances-accountability/evaluation/SSFFC\\_FinalReport\\_28Apr17.pdf?ua=1](http://www.who.int/about/finances-accountability/evaluation/SSFFC_FinalReport_28Apr17.pdf?ua=1) (accessed 28 April 2017).

ANNEX

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

**EXECUTIVE SUMMARY**

**WHO Evaluation Office**

## EXECUTIVE SUMMARY<sup>1</sup>

In 2012, the Sixty-fifth World Health Assembly adopted resolution WHA65.19, in which it decided to establish a Member State mechanism aimed at protecting public health and promoting access to affordable, safe, efficacious, and quality medical products, by promoting the prevention and control of substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products and associated activities. This resolution<sup>2</sup> renewed and re-established a mandate for the Secretariat and Member States in addressing SSFFC medical products from a public health perspective in a transparent and inclusive way. The Member State mechanism is supported by WHO and facilitated by the mechanism secretariat.

The goal of the mechanism is to protect public health and promote access to affordable, safe, efficacious and quality medical products, through effective collaboration among Member States and the Secretariat, for the prevention and control of SSFFC medical products and associated activities.

The review of the Member State mechanism was mandated by resolution WHA65.19 to be conducted in 2016. The Health Assembly subsequently decided to postpone the review by one year to 2017.<sup>3</sup> 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 of the Member State mechanism 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.

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

The objectives of the review were to respond to the following four 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?

The review sought the informed opinion of the primary stakeholders of the mechanism: all Member States (including health ministries and national/regional regulatory agencies), and WHO offices involved in supporting the implementation of the mechanism by Member States, such as the mechanism's secretariat and essential medicines regional advisers. Furthermore, nongovernmental organizations in official relations with WHO were made aware of this review and requested to express

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<sup>1</sup> Full report in English available on the WHO Evaluation Office website: [www.who.int/evaluation](http://www.who.int/evaluation) (accessed 21 April 2017).

<sup>2</sup> The resolution further decided to review the Member State mechanism after three years of operation.

<sup>3</sup> Decision WHA68(12).

interest to participate in it, at which point, the Evaluation Office provided them access to the online survey. The survey for the review was managed online through a secure WHO electronic platform.

The scope of the review covered the implementation of the eight strategies and action areas defined in the workplan of the Member State mechanism together with their relationship to the achievement of the objectives of the mechanism. The review estimated the extent of implementation of the workplan and explored its potential to achieve the corresponding objectives. The review also explored the factors that supported or hampered implementation of the workplan, and collected survey respondents' proposed options for improving the effectiveness of the mechanism.

The review was carried out through an online survey for the primary stakeholders of the Member State mechanism, key-informant interviews, an online survey for interested nongovernmental organizations and a document review.

There were 151 Member State representatives who responded to the survey, corresponding to 104 Member States across the six WHO regions. Of these, 36 countries provided two or more complete responses per country, and 68 other countries provided one complete response per country. The sample was adequate to generate useful estimates of stakeholders' views and experiences.

With regard to the distribution of respondents by the type of organization, national and regional regulatory agencies (77 respondents or 50%) and health ministries (65 respondents or 43%), were well represented. About 4% of respondents were from other governmental institutions.

Of the respondents, 91 (60%) were familiar with the work of the mechanism, either by serving on the Steering Committee (7 respondents), participating in one of the Working Groups (21 respondents) or attending some of the mechanism's meetings (46 respondents), or advising the delegates to the mechanism (17 respondents). Another 37% of respondents had some exposure and were interested in its outcomes.

Eleven nongovernmental organizations in official relations with WHO responded to the survey. Seven of them were based in the European Region, another three in the Region of the Americas, and one more in the Western Pacific Region. Seven of them indicated that they were at least moderately familiar with the work of the Member State mechanism.

Additional key informant in-depth interviews took place. A total of 14 informants, including four members of the Steering Committee and the Member State mechanism secretariat, were interviewed. The informants offered additional perspectives on the mechanism.

## **Findings**

The review found that the mechanism continues to be relevant, it plays a critical role in raising awareness of SSFFC medical products and Member States would want it to continue.

With regard to the extent to which the objectives of the mechanism have been achieved, there is a substantial consensus that the mechanism has made reasonable progress in this regard, given the initial challenges and time required to create the enabling environment for the effective functioning of the mechanism. Member States considered that the mechanism is an adequate global platform to promote the prevention, detection and response to SSFFC medical products and associated activities. They also expressed agreement with the objectives and workplan of the mechanism and noted the value of a number of its products and activities. Overall, stakeholders considered that the mechanism had

partially addressed the objectives established in 2012. A key achievement during this period has been the agreement on the definitions of SSFFC medical products (see document A70/23).

Essentially, the formal and informal organizational structures created as a result of the mechanism and the ensuing collaborative climate and trust that emerged are recognized as important and necessary intermediate achievements. The factors that emerged as being supportive were Steering Committee leadership and commitment, the supporting of the mechanism by WHO and the development of good products and the convening of expert and Steering Committee meetings.

However, the main gaps identified are: an unfinished technical agenda; limited coordination processes among the different actors involved in the work of the mechanism; and the inadequate systems of communication and dissemination of information between the mechanism and Member States, as illustrated by the limited reach of the products and activities of the mechanism. Better synergies and improved coordination and sharing of information with Member States, as well as processes linking all three levels of the Organization, could facilitate better strategic planning and coordination of relevant programmes as well as technical support to countries while fostering wider collaboration and engagement, making the mechanism stronger and more successful.

In addition, strengthened communication between Member States and the mechanism, including its secretariat, would facilitate better information flow and sharing of ideas and contribute to the output of the working groups. This would imply more advocacy to inform institutions, manufacturers and other actors about the SSFFC challenges and the achievements of the mechanism.

The review noted that the mechanism was under-resourced, in part as a consequence of not being properly prioritized within WHO and among the actors of the mechanism. The diversity of initial political perspectives and expectations about the mechanism and the evolving operating procedures and governance structure were seen as factors that may have delayed the achievement of the objectives.

When considering options for future action, the mechanism should revisit its current workplan in order to complete outstanding activities. Furthermore, this would also be an opportune moment to consider plans and activities for the next phase and secure sufficient funding to enable the effective delivery of its renewed mandate. Strategically, the mechanism should place greater emphasis on expanding its stakeholder base, involving Member States more actively as well as regulatory agencies and non-State actors, and consolidate its activities, products, processes and outreach to provide sustainable support to Member States.

## **Recommendations**

1. Members of the Steering Committee of the Member State mechanism to revisit the current workplan, ensuring outstanding activities within the workplan are completed, and consider plans and activities for the next phase.
2. Develop appropriate processes for effective coordination, communication and dissemination of information on main action areas and outputs.

Action points:

- (a) strengthen coordination and harmonize procedures between the mechanism and relevant technical teams in WHO at headquarters and regional levels, and between the mechanism and Member States;
- (b) establish better systems for regional communication and dissemination of information between the mechanism and Member States, including strengthening use of electronic platforms and focal point networks;
- (c) improve coordination and communication on SSFFC matters across the three levels of the Organization;
- (d) encourage active engagement of more Member States in the work of the mechanism.

3. Build and expand national capacity to address SSFFC medical products.

Action points:

- (a) provide training to national focal points on the prevention, detection and response to SSFFC medical products;
- (b) develop tools to support implementation of the mechanism's activities;
- (c) expand the number of Member States that are actively engaged in the process.

4. Secure sufficient additional resources for the mechanism to be able to achieve all of its objectives.

Action points:

- (a) the mechanism should support secretariat efforts to secure additional resources from Member States and the international donor community;
- (b) WHO's senior management should consider prioritizing support and funding for the mechanism secretariat.

5. Encourage the engagement of additional actors in the mechanism, including academia, manufacturers, nongovernmental organizations, civil society and related technical institutions at global, regional and country levels.

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