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## **Review of the Member State mechanism by the Health Assembly in 2017**

### **Proposed approach and modalities**

#### **Report by the Secretariat**

1. In 2012, the Sixty-fifth World Health Assembly adopted resolution WHA65.19, in which it decided to establish the Member State mechanism and to review the mechanism after three years of operation. The general goal of the mechanism<sup>1</sup> was to protect public health and promote access to affordable, safe, efficacious and quality medical products, by promoting – through effective collaboration among Member States and the Secretariat – the prevention and control of substandard/spurious/falsefully-labelled/falsified/counterfeit medical products and associated activities.
2. In 2015, the Sixty-eighth World Health Assembly considered the report of the third meeting of the Member State mechanism,<sup>2</sup> as well as decision EB136(1), and adopted decision WHA68(12), in which the Health Assembly decided to postpone the review of the mechanism by one year, to 2017, as proposed by the mechanism in its report.
3. The Steering Committee of the Member State mechanism met in Geneva on 14 and 15 September 2015, considered the various options presented by the Secretariat and decided to recommend to the mechanism that the review be conducted using the mechanism's existing structure, together with the current distribution of work between the Steering Committee and the plenary, which had proved itself to be efficient. If this approach were taken, the mechanism would instruct the Secretariat to start preparing the review following the forthcoming meeting of the mechanism, and to provide an update to the Steering Committee at its next meeting. The work for the review would be based as much as possible on electronic consultations with the regions.

#### **Proposed process**

4. The Secretariat is proposing the following process for the review:
  - (a) the Secretariat to identify criteria for review linked to the objectives set forth in resolution WHA65.19 and to develop terms of reference

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

<sup>2</sup> Document A68/33, Annex.

- (b) on the basis of the work in (a), the Secretariat to make proposals to the Steering Committee
- (c) the Secretariat to facilitate the conduct of surveys, including a web-based survey
- (d) the Steering Committee to review the final report and adopt recommendations, the Secretariat to facilitate this work
- (e) the Steering Committee to disseminate the findings to Member States and key stakeholders, the Secretariat to facilitate this work
- (f) the Secretariat to facilitate the preparation of documentation and its presentation for consideration by the mechanism.

5. The proposed process would involve a review of the mechanism in terms of its success in achieving the objectives set forth in resolution WHA65.19.<sup>1</sup> The aim would be to document achievements, gaps and remaining challenges, and to make recommendations on the way forward. For ease of reference, the objectives are restated below.

- (1) 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.
- (2) To strengthen national and regional capacities in order to ensure the integrity of the supply chain.
- (3) To exchange experiences, lessons learnt, best practices, and information on ongoing activities at national, regional and global levels.
- (4) 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.
- (5) To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries.
- (6) 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”.
- (7) 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.

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

(8) To promote cooperation and collaboration on surveillance and monitoring of “substandard/spurious/falsely-labelled/falsified/counterfeit medical products”.

(9) To further develop definitions of “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” that focus on the protection of public health.

### **Review survey**

6. It is proposed that a structured questionnaire should be developed by the Secretariat to gather information on progress made with respect to the objectives listed above; and that it should be sent out to all Member States, all nongovernmental organizations in official relations with WHO and active in the pharmaceutical field, and all focal points for the WHO Global Surveillance and Monitoring Project. All regional and country offices should also be requested to respond to the questionnaire. A similar discussion should be facilitated on the web in order to encourage feedback from Member States and the target audience listed above. It is suggested that the collated responses and suggested recommendations should be prepared by the Secretariat and then presented to the Steering Committee for its review and consideration. The intention would be to develop the questionnaire and then pilot it after the mechanism meetings of November 2015, with implementation to follow in early 2016. An update will be provided to the Steering Committee at its next meeting.

### **ACTION BY THE MECHANISM**

7. The Member State mechanism is invited to consider the proposed approach to and modalities for the review of the mechanism and either to approve them or to advise on other ways to implement the decision of the Health Assembly to review the Member State mechanism after three years of operation.

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