## FIFTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS Provisional agenda item 5

A/MSM/5/3 4 November 2016

## WHO's participation in the Global Steering Committee for Quality Assurance of Health Products

- 1. At its fourth meeting, in November 2015, the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products considered a report on the Global Steering Committee for Quality Assurance of Health Products, established by the Global Fund to Fight AIDS, Tuberculosis and Malaria in November 2014.
- 2. In response to a request made by Member States at the fourth meeting, the present document is submitted in order to provide clearer information on the nature, legal status and governance of the Global Steering Committee; on its participants; and on the issues that are the focus of its activities.
- 3. The Global Steering Committee for Quality Assurance of Health Products is a voluntary coalition of international institutions whose objective is to work together to reduce the public health risks posed by falsified medicines.<sup>2</sup> The initiative seeks to harness the ongoing work by various interested parties, in each of their areas of focus to ensure coordination and collaboration.
- 4. The Global Steering Committee has no legal status but is a coalition with an interest in the quality assurance of medical products and the risks posed by falsified medical products. The current core membership is as follows:
  - · The World Bank
  - The GAVI Alliance
  - UNDP
  - The United States Agency for International Development, USAID
  - United States Food and Drug Administration
  - The International Drug Purchase Facility, UNITAID
  - The United States President's Malaria Initiative
  - The New Partnership for Africa's Development
  - the International Criminal Police Organization, INTERPOL
  - United Nations Interregional Crime and Justice Research Institute

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<sup>&</sup>lt;sup>1</sup> Document A/MSM/4/8.

<sup>&</sup>lt;sup>2</sup> Presentation by the Global Fund delivered to the Steering Committee of the Member State mechanism on 14 September 2015.

- 5. The Global Fund has agreed to host the Global Steering Committee and support secretariat costs for a three-year period. The Chairman of the Global Fund chairs the Global Steering Committee. The Global Fund invited WHO to participate in this initiative, and this request was shared with the Steering Committee of the Member State mechanism in March 2015. The Steering Committee recommended that WHO observe, on a provisional basis, the meetings of the Global Steering Committee. Subsequently a presentation of the Global Steering Committee was provided by the Global Fund secretariat to the Steering Committee of the Member State mechanism in September 2015.
- 6. In addition to the Global Steering Committee, a Private Sector Advisory Group was established in 2016; its members are representatives of research-based and generic pharmaceutical manufacturers and the International Federation of Pharmaceutical Manufacturing Associations. The Group is currently chaired by the Global Fund and reports to the Global Steering Committee. This advisory group is in the early stages of development; although its role has not yet been clearly defined, it is likely to include data-sharing, awareness-raising and training. The WHO Secretariat does not attend its meetings, but an update of their discussions is provided at the Global Steering committee meetings.
- 7. The Global Steering Committee has explored the establishment of a trust fund to support and sustain its activities. The intention is to establish a fund in the United Kingdom of Great Britain and Northern Ireland, managed by an external audit company.
- 8. The main areas of focus of the Global Steering Committee are as follows:
  - Regulatory strengthening
  - · Data collection, analysis and strengthening
  - Public awareness
  - Enforcement capacity-building
- 9. At its fourth meeting, the Member State mechanism considered the Secretariat's participation in the Global Steering Committee. It noted various overlapping areas of activity between itself and the Global Steering Committee, and decided that the Secretariat could continue to observe the Committee's meetings on a provisional basis.
- 10. The Global Steering Committee reports that most significant progress has been made in relation to regulatory strengthening, specifically regarding the establishment of a spectral library of medicines for use with hand-held field detection devices that can be used by national regulatory authorities. The Committee has also supported enforcement activities in the African Region, providing one Member State with training, equipment and funding. The Committee is seeking to expand this support to other Member States.
- 11. A conference is in the early stages of planning and is tentatively scheduled to be held in the African Region in 2017.
- 12. The Global Steering Committee meets quarterly, and the next meeting is planned for early December 2016, hosted by the World Bank at its offices in Washington, DC.

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