World Health Organization

**FOURTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS**
**Provisional agenda item 8**

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# WHO's participation in the global steering committee for quality assurance of health products

## Report by the Secretariat

1. This document is submitted at the request of the Steering Committee of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products, and follows a presentation delivered to the Steering Committee in September 2015 from the Global Fund.

2. The Global Fund to Fight AIDS, Tuberculosis and Malaria has established a global steering committee for quality assurance of health products. The committee is a voluntary coalition of international institutions whose objective is to work together to reduce the public health risks posed by falsified medicines.

### Membership and structure

3. The core members of the global steering committee are primarily health financing institutions with global programmes that receive funding from many donors, and which not only procure significant amounts of medical products but also seek to strengthen the capacity of health systems in the recipient countries.

4. The Chairman of the Board also chairs the global steering committee for quality assurance of health products. The Global Fund secretariat provides the secretariat for the steering committee.

5. The core members of the global steering committee for quality assurance of health products are currently:

- World Bank
- The GAVI Alliance
- United Nations Development Programme (UNDP)
- United States President's Malaria Initiative
- USAID
- United States Food and Drug Administration
- UNITAID
- The New Partnership for Africa's Development
- INTERPOL

6. The global steering committee actively seeks to collaborate with the private sector and nongovernmental organizations to leverage its expertise, in-kind support and resources in furthering the work of working groups in five areas, namely:

(a) Strengthening of medicines regulatory authority

(b) Analysis and strengthening of data collection

(c) Public awareness raising

(d) Enforcement capacity building

(e) Public–private financing

## Collaboration between the global steering committee and the Member State mechanism

7. It is widely recognized that in order to tackle SSFFC medical products from an international, regional or national perspective there needs to be a degree of collaboration between all relevant stakeholders. Identifying synergies, sharing experience and coordinating activities can reduce duplication of effort and wasted resources. Such collaboration can also lead to a more consistent and coherent approach in dealing with the issue. The table below maps the workplans of the two initiatives.

| **WHO-Member State mechanism workplan[1]** | **Global steering committee working groups** |
|---|---|
| Strengthening and capacity building of national and regional drug regulatory authorities and quality-control laboratories (both national and regional level) | Medicines Regulatory Authority Strengthening |
| 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 | Data collection, analysis and strengthening |
| Communication, education and awareness raising | Public Awareness Raising |
| 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 | Overall objective of global steering committee |
| Identify actions, activities and behaviours that result in SSFFC medical products | Data collection, analysis and strengthening |
| Strengthen national and regional capacities in order to ensure the integrity of the supply chain | Medicines Regulatory Authority Strengthening |

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

| Collaboration on surveillance and monitoring | Data collection, analysis and strengthening |
|---|---|
| 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 | - |
| - | Enforcement Capacity Building |
| - | Public/Private Financing |

8. A degree of overlap exists between the working groups of the global steering group and the agreed eight-point workplan of the Member State mechanism in relation to three specific areas, namely: regulatory strengthening, communication/public awareness, and surveillance and monitoring/data analysis.

9. The risk of failing to collaborate in these areas of overlap may lead to the wastage of resources and the overburdening of Member States with a growing number of initiatives that may also be in competition with one another – generating confusion rather than clarity.

10. However there may be merit in certain well-targeted and aligned initiatives. The following paragraphs list three examples, covering each of the overlapping areas.

11. **Regulatory strengthening.** The initiative aims to provide Member States with an online image library for use in hand-held field screening devices currently being used in a number of Member States, particularly those that do not have access to quality-control laboratories. The library would include all WHO pre-qualified medicines as well as a number of other essential medicines and would allow a screening test to be carried out in the field. Where such tests failed, they could be followed by more detailed analysis in an appropriate laboratory.

12. **Communication, education and awareness raising.** The United Kingdom of Great Britain and Northern Ireland is about to commence leading the Member State mechanism's prioritized activity on this topic and may benefit from discussion with those mapping current awareness initiatives for the global steering committee. The latter activity is being led by USAID for the global steering committee.

13. **Surveillance and monitoring of SSFFC medical products.** The Global Fund to Fight AIDS, Tuberculosis and Malaria has discovered falsified versions of antimalarials bearing the logo of the Global Fund's Affordable Medicines Facility malaria (AMFm) programme. These medicines, involving both generic and innovator products, are also WHO prequalified medicines and are reported to the WHO Surveillance and Monitoring System and the national drug regulatory authorities. Equally, national focal points within the surveillance and monitoring network report cases of falsified and diverted Global Fund medicines to WHO, which are shared with the Global Fund. These reports have led to a number of global medical product rapid alerts issued by WHO.

14. The Secretariat has informed the Steering Committee of the Member State mechanism of the emerging initiative from the global steering committee and currently has observer status until a decision is reached by the Member State mechanism as to further collaboration.

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