World Health Organization

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

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# Budget and cost implications and implementation of the workplan, and the outcome of the Open-ended Working Group to Identify the Actions, Activities and Behaviours that Result in Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit Medical Products, including time frames

1. This document presents the estimated financial requirements for 2014–2015 for the implementation of the proposed workplan of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products as agreed by the Steering Committee at their meeting held in Geneva on 26 July 2013. The Steering Committee based its discussions on the outcome document of the Informal Technical Consultation on the remaining elements of the workplan, which met in Geneva on 25 July 2013.

## General goal

2. The general goal of the workplan is to protect public health and promote access to affordable, safe, efficacious and quality medical products, promote, through effective collaboration among Member States and the Secretariat, the prevention and control of substandard/spurious/falsely-labelled/falsified/counterfeit medical products and associated activities.

## Financial requirements

3. Since 2011, when the Member State mechanism was established, WHO's implementation of the work related to prevent and control SSFFC medical products has been largely financed by voluntary contributions from the governments of Argentina, Brazil, the Netherlands, Switzerland, and the United States of America. The estimated cost of the SSFFC programme is provided in the document containing the financial and administrative implications for the Secretariat of resolution EB130.R13 on substandard/spurious/falsely-labelled/falsified/counterfeit medical products.[1]

## Objectives and estimated cost of workplan implementation

4. The estimated costs given below are biennial and cover the Secretariat activities (organizing the annual meeting, supporting Member States).

[1] See document EB130/2012/REC/1. Annex 6 Financial and administrative implications for the Secretariat of resolutions and decisions adopted by the Executive Board. For resolution EB130.R13, the estimated cost and staffing implications are provided in subparagraph 3(a). The total costs covering a 3 year period (2012–2015) are between US$ 3.56 million and US$ 4.84 million (staff between US$ 2.72 million and US$ 4.00 million; activities US$ 840 000). This is a conservative estimation based on a single annual meeting of the Member State Mechanism.

5. The eight objectives agreed in the proposed workplan are also set out below, together with the estimated costs of implementation for the biennium 2014–2015. Reference is made to the overall costs of the Secretariat, logistics for hosting meetings, travel assistance for least developed countries, translation/interpretation and coordination of implementation. Specifically, US$ 480 000 (representing approximately 5% of the total budget) are available for implementation in 2014 and an additional figure of US$ 500 000 is expected in 2015 under the current surveillance project. The combined total represents 10% of the overall budget for the biennium 2014–2015.

## Outcome

6. The sum of the different activities mentioned in the proposal will lead to knowledge creation, surveys, training, discussion, guidelines, a website etc. All these outputs together will contribute to the final outcome: to protect public health and reduce the harm from substandard/spurious/falsely-labelled/falsified/counterfeit medical products.

| **Objectives and the estimated cost of implementing the workplan objectives** | | |
|---|---|---|
| | | Budget (US$) |
| Overall | Governance and management cost of the Member State mechanism | 2 566 500 |
| | *Including: organizing Member State mechanism and Steering Committee meetings, coordination of the activities; implementation by headquarters and regional offices.* | |
| Objective 1 | Strengthening and building capacity of national and regional regulatory authorities and quality control laboratories (both national and regional level) (related to objective 5) | 1 758 900 |
| | *Including: country assessments, guidelines for Standard Operating Procedures for laboratories on SSFFC, training seminars.* | |
| Objective 2 | 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 *(related to objectives 1 and 3)* | 2 097 500 |
| | *Including: research, expert meeting, publication of guidelines on authentication and detection technologies and methodologies, track and trace technologies and methodologies/models, and cost-effective prevention and detection.* | |
| Objective 3 | Communication, education and awareness raising *(related to all objectives)* | 1 066 500 |
| | *Including: tailor-made communication guides, advocacy action plan, up-to-date SSFFC website* | |
| Objective 4 | 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 | 988 500 |
| | *Including: regional seminars with stakeholders, network creation* | |
| Objective 5 | Identify actions, activities and behaviours that result in SSFFC medical products *(related to objective 4)* | Done |
| | *The open-ended working group to identify the actions, activities and behaviours that result in SSFFC medical products (Geneva 23 and 24 July 2013) listed the behaviours which can result in SSFFC medical products* | |

| **Objectives and the estimated cost of implementing the workplan objectives** | | |
|---|---|---|
| | | Budget (US$) |
| Objective 6 | Strengthen national and regional capacities in order to ensure the integrity of the supply chain *(related to objectives 1, 2 and 4)* | 2 836 400 |
| | *Including: regional meetings and seminars, tailor-made toolkit, utilizing current collaboration by building regional networks* | |
| Objective 7 | Collaboration on surveillance and monitoring *(related to objective 8)* | 903 050 |
| | *Including: improve and extend the WHO reporting system, issuing rapid alerts, reporting database, training* | |
| Objective 8 | 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 *(related to objective 6)* | 729 650 |
| | *Including policies on access to affordable medical products* | |
| **Total cost of implementation of the workplan objectives** | | **12 947 000** |

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