



Substandard/spurious/falsely-labelled/ falsified/counterfeit medical products

Report by the Director-General

1. The attached document EB134/25 was considered and noted by the Executive Board at its 134th session.¹

ACTION BY THE HEALTH ASSEMBLY

2. The Health Assembly is requested to note the report.

¹ See the summary records of the Executive Board at its 134th session, eighth meeting, section 3 (document EB134/2014/REC/2).



**World Health
Organization**

**EXECUTIVE BOARD
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Substandard/spurious/falsely-labelled/ falsified/counterfeit medical products

Report by the Director-General

The Director-General has the honour to transmit to the Executive Board at its 134th session the report of the Second Meeting of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products (see Annex), which met in Geneva on 28 and 29 November 2013.¹

¹ The goal, objectives, and terms of reference for this meeting were approved by the Sixty-fifth World Health Assembly in resolution WHA65.19, and are provided in the Annex to the resolution.

ANNEX

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

1. The second meeting of the Member State Mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products was held on 28 and 29 November 2013 in Geneva and was chaired by Dr Paul Botwev Orhii of Nigeria with the following vice-chairpersons: Dr Maximiliano Derecho on behalf of Dr Carlos Chiale of Argentina; Ms Lou Valdez of the United States of America; Dr Reida El Oakley of Libya; Ms Fareha Bugti of Pakistan; Mr Nimo Ahmed of the United Kingdom of Great Britain and Northern Ireland; Ambassador Carole Lanteri of Monaco; Mr Rolliansyah Soemirat of Indonesia; Mr Hemant Kotalwar of India; Mr Ding Jianhua of China; and Ms Ruth Lee of Singapore. The session was attended by 76 Member States and one regional economic integration organization.
2. The Mechanism considered and adopted the non-exhaustive list of actions, activities and behaviours that result in SSFFC medical products, as contained in the report of the Open-ended Working Group to Identify the Actions, Activities and Behaviours that result in SSFFC medical products (see Appendix 1). The Mechanism emphasized that the scope of the Member State Mechanism excludes trade and intellectual property considerations, in accordance with paragraph 4 of World Health Assembly resolution WHA65.19.
3. The Mechanism reviewed the report of the Steering Committee of the Member State Mechanism on SSFFC and adopted the Steering Committee's suggestions for finalizing the work plan. The work plan is attached, as amended by the Mechanism, in Appendix 2.¹
4. The Mechanism welcomed the Secretariat's presentation regarding the WHO Global Surveillance and Monitoring Project and encouraged Member States to participate in and contribute to the development of the Project.
5. The Mechanism considered a proposal by Argentina to develop recommendations for health authorities to detect and deal with actions, activities and behaviours that result in SSFFC medical products as a way to continue the work of the Open-ended working group on actions, activities and behaviours that result in SSFFC medical products, as well as a proposal by India on element 5(b) of the work plan on the identification of activities and behaviours that fall outside the mandate of the Mechanism. The Mechanism agreed that Argentina and India would lead technical discussions on these issues, respectively, using an electronic platform hosted by the Secretariat. It was further agreed that an informal technical meeting, open to all Member States,² to finalize the outcomes of the electronic consultations would be held before the third meeting of the Member State mechanism.
6. The Mechanism further agreed to request the Steering Committee to consider and prioritize proposals for implementation of the work plan, to be reviewed by the third meeting of the Mechanism.

¹ The Mechanism amended the following elements of the work plan: 6(d), 6(e), 6(f), 6(g), 6(h), and 7(b).

² Where applicable, also regional economic integration organizations.

7. The Mechanism considered the presentation and report on the budget and cost implications and implementation of the work plan, and the outcome of the Open-ended Working Group to Identify Actions, Activities and Behaviours that Result in Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit Medical Products, including time frames.¹ The Mechanism endorsed the budget, as amended,² attached at Appendix 3. The Mechanism was highly concerned by the funding gap existing at this stage and strongly recommended that the Executive Board request the Director-General to provide the Sixty-Seventh World Health Assembly with a comprehensive update on the financing of the work plan, and encourage Member States and other WHO donors to consider funding the work plan of the Member State mechanism within the ongoing WHO financing dialogue process.

8. The Mechanism considered a report by the Secretariat on Governance,³ and agreed to continue with the rotation of the chairmanship of the Mechanism and the Steering Committee among the vice-chairpersons, as recommended in World Health Assembly decision WHA66(10). It acknowledged that the interim nature of this arrangement will not replace the appointment of a chairperson as required by the decision of the first meeting of the Member State mechanism. The Member State mechanism agreed that the chairmanship should rotate among the regions in alphabetical order on a yearly basis, at the end of the World Health Assembly. The representative of Nigeria will continue to chair until the end of the Sixty-Seventh World Health Assembly in May 2014, after which the chairmanship will be provided by one of the vice-chairpersons from the Region of the Americas until the end of the Sixty-eighth World Health Assembly in 2015. Member States shall receive official notification at the conclusion of the World Health Assembly.

9. On the issue of Governance, it was further agreed that the vice-chairpersons of the Mechanism would act on behalf of their respective Member States rather than in their personal capacity and that the Steering Committee meetings could be observed remotely by Member States through electronic means.

10. The Member State mechanism considered an item including three topics proposed for discussion by the Open-ended Working Group and the Steering Committee on: advertising that misleads the public and purchasing entities, corruption and conflict of interest, and lack of effective labelling of medical products, as well as a proposal by the Russian Federation on the first of these topics. It was pointed out that on the subject of advertising, there are existing WHO ethical criteria that may be reviewed.⁴

11. The Mechanism decided that the next meeting would be held during the week of 27 October 2014. The third meeting of the Member State mechanism will be preceded by a meeting of the Steering Committee.

12. The Member State mechanism requests the Director-General to transmit the report of its second meeting to the Sixty-Seventh World Health Assembly through the Executive Board at its 134th session.

¹ Document A/MSM/2/4.

² The Mechanism amended the column on costs associated with Objective 5 “Identify actions, activities and behaviours that result in SSFFC medical products (*related to objective 4*)” of document A/MSM/2/4.

³ Document A/MSM/2/5.

⁴ See resolution WHA41.17; document WHA41/1988/REC/1, page 46.

Appendix 1

**Actions, Activities and Behaviours that Result in Substandard/Spurious/
Falsely-labelled/Falsified/Counterfeit Medical Products**

1. The Open-ended Working Group to Identify the Actions, Activities and Behaviours that Result in Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit Medical Products, in order to protect public health and promote access to affordable, safe, efficacious, and quality medical products, has identified the following actions, activities, and behaviours that result in substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products. This is a non-exhaustive list that could be subject to revisions and adjustments in the future. The guiding principle is to prevent and reduce the risk to public health from SSFFC medical products, ensuring that only medical products meeting the national and/or regional regulatory authority requirements are manufactured, imported, distributed and supplied:

- manufacturing medical products in establishments that are not authorized by the national and/or regional regulatory authority;
- manufacturing medical products or their packaging or their labelling without registration or approval by the national and/or regional regulatory authority;
- modifying accompanying information of the medical products and changing their packaging and extending the use-before date or expiration date of the products that misleads the public and/or purchasing entities;
- substituting the contents of the medical product using the authorized packaging;
- importing, exporting, distributing, including transporting, supplying, selling, including through the internet, as appropriate, and storing medical products without compliance to applicable national and/or regional regulations and requirements;
- manufacturing, importing, distributing, supplying or selling medical products:
 - (a) without registration or approval or authorization by the national regulatory authority; or
 - (b) using an authorization that does not exist; or
 - (c) using without permission an authorization already granted to another¹ by a national and/or regional regulatory authority;
- manufacturing medical products which replicate registered medical products or their packaging without authorization of the national and/or regional regulatory authority;

¹ The term “another” refers to products or manufacturers, importers, distributors, suppliers, or sellers of medical products.

- failing to comply with good practices of manufacturing, distribution, transportation and storage of medical products, as set out by the national and/or regional regulatory authority;
- importing, exporting, distributing, including transporting, storing, supplying or selling medical products obtained from an unauthorized or unknown origin;
- manufacturing medical products that violate the formula or the data contained in the registration file as approved or accepted by the national and/or regional regulatory authority;
- modifying the packaging and/or the labelling, without complying with national and/or regional regulations and without authorization from the national and/or regional regulatory authority.

Appendix 2

Work plan of the Member State Mechanism on substandard/spurious/ falsely-labelled/falsified/counterfeit medical products

1. Strengthening and capacity building of national and regional regulatory authorities and quality control laboratories (both national and regional level) *(related to Objective 5)*

- (a) Identify strengths and weaknesses of national/regional regulatory capacity.
- (b) Identify actions to improve Member State/regional regulatory capacities.
- (c) Develop and utilize training programmes for capacity building in countries/regions with identified needs.
- (d) Promote availability of adequate resources for capacity building.

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, 3)*

- (a) Exchange experiences, lessons learnt and information about authentication and detection technologies and methodologies.
- (b) Exchange experiences, lessons learnt and information about Track and Trace technologies and methodologies and models.
- (c) Exchange experiences, best practices and lessons learnt on cost-effective prevention, detection and control strategies for SSFFC medical products.

3. Communication, education and awareness raising *(related to all Objectives)*

- (a) Vigilance and awareness education among consumers, health professionals and industry.
- (b) Advocacy to political leadership.

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

5. Identify actions, activities and behaviours that result in SSFFC medical products *(related to Objective 4)*

- (a) Identify the activities and behaviours that result in SSFFC medical products being prevented and controlled due to the health risk they present to the population.
- (b) Identify those activities and behaviours that fall outside the mandate of the mechanism and separate them from the list of activities and behaviours aforementioned.

6. Strengthen national and regional capacities in order to ensure the integrity of the supply chain (related to Objectives 1, 2 and 4)

- (a) Identify actions and activities for prevention and control of SSFFC medical products.
- (b) Promote the control of distribution channels to prevent SSFFC medical products and strengthen good distribution practices.
- (c) Identify actions and activities to address internet sales that contribute to SSFFC medical products.
- (d) Make policy recommendations for Member States and the WHO action/response plan to prevent and control the activities and behaviours identified under objective 4 in resolution WHA65.19, suitable to the scope of the Member State mechanism.
- (e) Where appropriate, support the development of guidelines for national/regional dedicated programme officer or office to address SSFFC medical products in coordination with the national/regional regulatory authority.
- (f) Develop detection strategies and corresponding responses/actions to be taken upon discovery of SSFFC medical products.
- (g) Encourage national and/or regional regulatory authorities to have up-to-date registers of manufacturers, importers, distributors and medical products and to be willing to reveal their status.
- (h) Identify a single point of contact from each national/regional regulatory authority, for the purposes of SSFFC medical products, and establish a network.

7. Collaboration on surveillance and monitoring (related to Objective 8)

- (a) Development of methodologies, criteria and tools for data collection and analysis.
- (b) Sharing of information on relevant signals, alerts and incidents, including through the network of single points of contact and WHO's global surveillance system; this might include consultation, cooperation and collaboration with relevant stakeholders, as appropriate, in a transparent and coordinated manner from a public health perspective.
- (c) Increase regional and global cooperation.

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)

- (a) Exchange experiences, best practices, and information relating to identifying measures that address access to quality, safe, efficacious, and affordable medical products – including, but not limited to, the supply and use of generic medical products – and contribute to the existing work of WHO.

- (b) Make recommendations to further enhance WHO access programmes to mitigate the risks of SSFFC medical products available to the public.
- (c) Increase the knowledge and understanding about the links between the lack of accessibility/affordability and its impact on the emergence of SSFFC medical products and recommend strategies to minimize that impact.
- (d) Contribute to raising awareness of policies that hinder access to affordable medical products.
- (e) Collaborate and contribute to global efforts through stronger regulatory systems, in order to work towards making essential/life-saving medical products affordable.
- (f) Contribute to the work of other areas of WHO in its efforts at global, regional and country levels for local manufacturing to promote access to quality, safe, efficacious and affordable medical products, recognizing the need for strong regulatory systems.

Appendix 3

Budget and cost implications and implementation of the work plan, 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 work plan 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 work plan that met in Geneva on 25 July 2013.

General goal

2. The general goal of the work plan is to protect public health and promote access to affordable, safe, efficacious and quality medical products, and 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 work plan implementation

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

5. The eight objectives agreed in the proposed work plan 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

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 three-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.

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 work plan objectives		
		Budget (US\$)
Overall	Governance and management cost of the Member State mechanism	2 566 500
	<i>Including: organizing Member State mechanism and Steering Committee meetings, coordination of the activities; implementation by headquarters and regional offices.</i>	
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
	<i>Including: country assessments, guidelines for Standard Operating Procedures for laboratories on SSFFC, training seminars.</i>	
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
	<i>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.</i>	
Objective 3	Communication, education and awareness raising (related to all objectives)	1 066 500
	<i>Including: tailor-made communication guides, advocacy action plan, up-to-date SSFFC website</i>	
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
	<i>Including: regional seminars with stakeholders, network creation</i>	
Objective 5	Identify actions, activities and behaviours that result in SSFFC medical products (related to objective 4)	To be determined
	<i>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</i>	
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
	<i>Including: regional meetings and seminars, tailor-made toolkit, utilizing current collaboration by building regional networks</i>	

Objectives and the estimated cost of implementing the work plan objectives		
		Budget (US\$)
Objective 7	Collaboration on surveillance and monitoring (<i>related to objective 8</i>)	903 050
	<i>Including: improve and extend the WHO reporting system, issuing rapid alerts, reporting database, training</i>	
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 (<i>related to objective 6</i>)	729 650
	<i>Including policies on access to affordable medical products</i>	
Total cost of implementation of the work plan objectives		12 947 000

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