

Advance, Unedited Version

(Annex to draft resolution)

**Member State mechanism on SSFFC
Goals, objectives and terms of reference**

General goal

In order to protect public health and promote access to affordable, safe, efficacious and quality medical products, promote, through effective collaboration among Member States and WHO, the prevention and control of SSFFC¹ medical products and associated activities. *CONSENSUS*

Objectives

- 1) To identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies and control of SSFFC medical products in order to strengthen national and regional capacities. *CONSENSUS*
- 2) To strengthen national and regional capacities in order to ensure the integrity of the supply chain. *CONSENSUS*
- 3) To exchange experiences, lessons learnt, best practices, and information on ongoing activities at national, regional and global levels. *CONSENSUS*
- 4) To identify actions, activities and behavior that result in SSFFC medical products and make recommendations, including for improving the quality, safety and efficacy of medical products. *CONSENSUS*
- 5) To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and LDCs. *CONSENSUS*
- 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 SSFFC. *CONSENSUS*
- 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. *CONSENSUS*
- 8) To promote cooperation and collaboration on surveillance and monitoring of SSFFC medical products. *CONSENSUS*
- 9) To further develop definitions of SSFFC medical products that focus on the protection of public health. *CONSENSUS*

¹ The mechanism shall use the term SSFFC until a definition has been endorsed by the Governing Bodies

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Structure

- 1) The Member State mechanism will be open to all Member States². The Member State mechanism should include expertise in national health and medical products regulatory matters. *CONSENSUS*
- 2) The Member State mechanism may establish subsidiary working groups from among its members to consider and make recommendations on specific issues. *CONSENSUS*
- 3) Regional groups will provide input into the Member State mechanism as appropriate. *CONSENSUS*
- 4) The mechanism shall make use of existing WHO structures. *CONSENSUS*

Meetings

- 1) The Member State mechanism should meet not less than once a year and in additional sessions as needed. *CONSENSUS*
- 2) The default venue for the Member State mechanism, and its subsidiary working groups, will be Geneva. Meetings may, however, be held from time to time outside of Geneva taking into account regional distribution, overall cost and cost-sharing, and relevance to the agenda. *CONSENSUS*

Relations with other stakeholders and experts

- 1) As needed the Member State mechanism should seek expert advice on specific topics, following standard WHO procedures for expert groups. *CONSENSUS*
- 2) As needed the Member State mechanism will invite other stakeholders to collaborate and consult with the group on specific topics. *CONSENSUS*

Reporting and review

- 1) The functioning of the mechanism shall be reviewed by the WHA after three years of its operation. *CONSENSUS*
- 2) Report to the WHA through the EB on progress and any recommendations annually as a substantive item for the first 3 years and every 2 years thereafter. *CONSENSUS*

² including, where applicable, regional economic integration organizations

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Transparency and conflict of interest

- 1) The Member State mechanism, including all invited experts, should operate in a fully inclusive and transparent manner. *CONSENSUS*

- 2) Possible conflicts of interest shall be disclosed and managed in accordance with the policies and practice of WHO. *CONSENSUS*