World Health Organization

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

A/MSM/5/4 Add.1
4 November 2016

Review of the Member State mechanism on substandard/spurious/falsely-labelled/ falsified/counterfeit medical products

Survey questionnaire

1. In order to protect public health and promote access to affordable, safe, efficacious and quality medical products, the Sixty-fifth World Health Assembly adopted resolution WHA65.19 (2012), in which it decided to establish a mechanism whose general goal is to promote effective collaboration among Member States and the Secretariat, for the prevention, detection and response to substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products and associated activities.

2. In line with the terms of reference of the Member State mechanism,[1] the WHO Evaluation Office is conducting a review of the mechanism in order to gather evidence on its progress. The review, which will make use of a questionnaire, includes the functioning and work of the mechanism during its first four years, namely, for the period 2012−2016. The findings of the review will be presented to the Seventieth World Health Assembly in May 2017. It is expected that the questionnaire will document achievements, gaps and remaining challenges that will enable recommendations on the way forward.

3. The review will focus on the following high-level criteria:

   (a) The perceived relevance of the mechanism, its objectives and actions undertaken

   (b) The benefits gained by the actions undertaken under the mechanism

   (c) The gaps and challenges that have hindered the achievement of objectives and the success factors that have contributed to the achievements of the mechanism

   (d) The overall appraisal of the mechanism

4. Thank you for responding to the following questionnaire.

[1] See document WHA65/2012/REC/1, resolution WHA65.19, Annex.

A. Affiliation of respondent

1. In which country do you work?

Drop-Down menu with list of countries

2. What type of institution do you work for?

- ☐ Ministry of Health
- ☐ National/Regional Regulatory Agency
- ☐ Governmental institution other than those listed above
- ☐ Academia/research Institution/other public health-related agency
- ☐ Nongovernmental organizations in official relations with WHO[1] active in the pharmaceutical field
- ☐ WHO country offices
- ☐ WHO regional offices
- ☐ WHO headquarters
- ☐ Other (please specify): _____

3. How would you describe your knowledge about the Member State mechanism on SSFFC medical products?

- ☐ I am in general very familiar with it
- ☐ I have moderate knowledge about it
- ☐ I don't know much about the process, but I know (some) of its outcomes
- ☐ I hardly know anything about it
- ☐ I had never heard of it before receiving this questionnaire

4. What is your relationship with the mechanism?

Please click all responses that apply.

- ☐ I am, or have been, a member of the Steering Committee
- ☐ I am, or have been, a member of a working group of the mechanism
- ☐ I have attended some of the meetings of the mechanism
- ☐ I have provided direct advice to the mechanism or to delegates participating in the mechanism
- ☐ I work or collaborate with the secretariat of the mechanism
- ☐ I have used some of the outputs of the mechanism in my country or work environment
- ☐ I am interested at the outcomes of the mechanism
- ☐ None of the above /other (please specify): _____

[1] Following the adoption by the Sixty-ninth World Health Assembly of the Framework of Engagement with Non-State Actors (resolution WHA69.10), the nongovernmental organizations concerned fall within the group of non-State actors in official relations with WHO.

B. Relevance of the mechanism and its actions

5. The World Health Assembly established a mechanism for international collaboration among Member States to address global issues of relevance from a public health perspective related to substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products. Please indicate your level of agreement with the following statements.

	(1) Strongly disagree	(2) Disagree	(3) Neutral	(4) Agree	(5) Strongly agree	(–) Don't know
A Member State mechanism is an adequate platform to foster international collaboration to promote the prevention, detection and response to SSFFC medical products at global level	☐	☐	☐	☐	☐	☐
A Member State mechanism is an adequate platform to foster international collaboration to promote the prevention, detection and response to SSFFC medical products at regional level	☐	☐	☐	☐	☐	☐
A Member State mechanism is an adequate platform to foster international collaboration to promote the prevention, detection and response to SSFFC medical products at national level	☐	☐	☐	☐	☐	☐

If you want to further elaborate on your opinion regarding these statements, please use the text field below:

[*open question*]

6. To what extent do you consider the following objectives are relevant to promoting the prevention, detection and response to substandard/spurious/falsely-labelled/falsified/counterfeit medical products and associated activities from a public health perspective?

	(1) Not relevant	(2) Hardly relevant	(3) Moderately relevant	(4) Highly relevant	(5) Extremely relevant	(–) Don't know
Objective 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	☐	☐	☐	☐	☐	☐
Objective 2. To strengthen national and regional capacities in order to ensure the integrity of the supply chain	☐	☐	☐	☐	☐	☐
Objective 3. To exchange experiences, lessons learned, best practices, and information on ongoing activities at national, regional and global levels	☐	☐	☐	☐	☐	☐
Objective 4. To identify actions, activities and behaviours that result in SSFFC medical products and make recommendations, including for improving the quality, safety and efficacy of medical products	☐	☐	☐	☐	☐	☐
Objective 5. To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries	☐	☐	☐	☐	☐	☐
Objective 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 medical products	☐	☐	☐	☐	☐	☐

	(1) Not relevant	(2) Hardly relevant	(3) Moderately relevant	(4) Highly relevant	(5) Extremely relevant	(–) Don't know
Objective 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	☐	☐	☐	☐	☐	☐
Objective 8. To promote cooperation and collaboration on surveillance and monitoring of SSFFC medical products	☐	☐	☐	☐	☐	☐
Objective 9. To further develop definitions of SSFFC medical products that focus on the protection of public health	☐	☐	☐	☐	☐	☐

7. Is there any additional objective that you consider important to add?

☐ No

☐ Yes

If yes, please specify: _____

8. Since 2012, the Member State mechanism has been working on various activities in order to achieve its objectives. Do you know or have you received any information about the following products?

	(1) I am very familiar with this product or activity	(2) I have some knowledge about this product or activity	(3) I hardly know anything about this product or activity	(4) I have never heard of this product or activity
Document on actions, activities and behaviours that result in SSFFC medical products	☐	☐	☐	☐
Recommendations for health authorities to detect and deal with actions, activities and behaviours that result in SSFFC medical products	☐	☐	☐	☐
Recommendations for health authorities engaged in the detection of SSFFC medical products and the establishment of a strengthening and tool-generating programme to contribute to Member States' training	☐	☐	☐	☐
Creation of a Global Focal Point Network on SSFFC medical products as an ongoing virtual exchange forum	☐	☐	☐	☐
Document on existing technologies and "track and trace" models in use and to be developed by Member States	☐	☐	☐	☐
Report on the current state of affairs of WHO areas working on the issue of access to quality, safe, efficacious and affordable medical products	☐	☐	☐	☐
Recommendations for effective risk communication and for awareness campaigns on SSFFC medical products	☐	☐	☐	☐
A study on the public health and socioeconomic impact of SSFFC medical products	☐	☐	☐	☐
Governance, management, and secretariat costs to support the above activities	☐	☐	☐	☐
Report on actions, activities and behaviours that fall outside the mandate of the Member State mechanism	☐	☐	☐	☐
Definitions on SSFFC medical products created by a group of experts from national medicines regulatory authorities	☐	☐	☐	☐

9. Regarding these products, how would you rate their relevance to promote the prevention, detection and response to substandard/spurious/falsely-labelled/falsified/counterfeit medical products from a public health perspective?

	(1) Not relevant	(2) Hardly relevant	(3) Moderately relevant	(4) Highly relevant	(5) Extremely relevant	(–) Don't know
Document on actions, activities and behaviours that result in SSFFC medical products	☐	☐	☐	☐	☐	☐
Recommendations for health authorities to detect and deal with actions, activities and behaviours that result in SSFFC medical products	☐	☐	☐	☐	☐	☐
Recommendations for health authorities engaged in the detection of SSFFC medical products and the establishment of a strengthening and tool-generating programme to contribute to Member States' training	☐	☐	☐	☐	☐	☐
Creation of a Global Focal Point Network on SSFFC medical products as an ongoing virtual exchange forum	☐	☐	☐	☐	☐	☐
Document on existing technologies and "track and trace" models in use and to be developed by Member States	☐	☐	☐	☐	☐	☐
Report on the current state of affairs of WHO areas working on the issue of access to quality, safe, efficacious and affordable medical products	☐	☐	☐	☐	☐	☐
Recommendations for effective risk communication and for awareness campaigns on SSFFC medical products	☐	☐	☐	☐	☐	☐
A study on the public health and socioeconomic impact of SSFFC medical products	☐	☐	☐	☐	☐	☐
Governance, management, and secretariat costs to support the above activities	☐	☐	☐	☐	☐	☐
Report on actions, activities and behaviours that fall outside the mandate of the Member State mechanism	☐	☐	☐	☐	☐	☐
Definitions on SSFFC medical products created by a group of experts from national medicines regulatory authorities	☐	☐	☐	☐	☐	☐

10. Is there any additional product that you consider important to add?

☐ No

☐ Yes

If yes, please specify: _____

11. To what extent have the products listed in the following table been used, adopted or influenced policy and practice in your country or work environment? Please rate the extent of use, adoption or influence of these products based on your knowledge, and if possible provide examples.

Products of the mechanism	(1) None	(2) Little	(3) Moderate	(4) High	(5) Very high	(–) Don't know	**Examples**
Document on actions, activities and behaviours that result in SSFFC medical products	☐	☐	▫	☐	☐	☐	
Recommendations for health authorities to detect and deal with actions, activities and behaviours that result in SSFFC medical products	☐	☐	▫	☐	☐	☐	
Recommendations for health authorities engaged in the detection of SSFFC medical products and the establishment of a strengthening and tool-generating programme to contribute to Member States' training	☐	☐	▫	☐	☐	☐	
Creation of a Global Focal Point Network on SSFFC medical products as an ongoing virtual exchange forum	☐	☐	▫	☐	☐	☐	
Document on existing technologies and "track and trace" models in use and to be developed by Member States	☐	☐	▫	☐	☐	☐	
Report on the current state of affairs of WHO areas working on the issue of access to quality, safe, efficacious and affordable medical products	☐	☐	▫	☐	☐	☐	
Recommendations for effective risk communication and for awareness campaigns on SSFFC medical products	☐	☐	▫	☐	☐	☐	
A study on the public health and socioeconomic impact of SSFFC medical products	☐	☐	▫	☐	☐	☐	
Governance, management, and secretariat costs to support the above activities	☐	☐	▫	☐	☐	☐	
Report on actions, activities and behaviours that fall outside the mandate of the Member State mechanism	☐	☐	▫	☐	☐	☐	
Definitions on SSFFC medical products created by a group of experts from national medicines regulatory authorities	☐	☐	▫	☐	☐	☐	

12. What is your extent of satisfaction with the products being developed by the mechanism? Please rate your satisfaction and further elaborate your opinion, if desired.

Products started by the mechanism	(1) Not at all satisfied	(2) Slightly satisfied	(3) Moderately satisfied	(4) Very satisfied	(5) Extremely satisfied	(–) Don't know	**Further justification**
Document on actions, activities and behaviours that result in SSFFC medical products	☐	☐	☐	☐	☐	☐	
Recommendations for health authorities to detect and deal with actions, activities and behaviours that result in SSFFC medical products	☐	☐	☐	☐	☐	☐	
Recommendations for health authorities engaged in the detection of SSFFC medical products and the establishment of a strengthening and tool-generating programme to contribute to Member States' training	☐	☐	☐	☐	☐	☐	
Creation of a Global Focal Point Network on SSFFC medical products as an ongoing virtual exchange forum	☐	☐	☐	☐	☐	☐	
Document on existing technologies and "track and trace" models in use and to be developed by Member States	☐	☐	☐	☐	☐	☐	
Report on the current state of affairs of WHO areas working on the issue of access to quality, safe, efficacious and affordable medical products	☐	☐	☐	☐	☐	☐	

Products started by the mechanism	(1) Not at all satisfied	(2) Slightly satisfied	(3) Moderately satisfied	(4) Very satisfied	(5) Extremely satisfied	(–) Don't know	**Further justification**
Recommendations for effective risk communication and for awareness campaigns on SSFFC medical products	☐	☐	☐	☐	☐	☐	
A study on the public health and socioeconomic impact of SSFFC medical products	☐	☐	☐	☐	☐	☐	
Governance, management, and secretariat costs to support the above activities	☐	☐	☐	☐	☐	☐	
Report on actions, activities and behaviours that fall outside of the mandate of the Member State mechanism	☐	☐	☐	☐	☐	☐	
Definitions on SSFFC medical products created by a group of experts from national medicines regulatory authorities	☐	☐	☐	☐	☐	☐	

FILTER ON:

THE FOLLOWING QUESTIONS SHADOWED IN GREY WILL ONLY APPEAR TO RESPONDENTS WHO SELECTED AT LEAST ONE OF THE FOLLOWING RELATIONSHIPS WITH THE MECHANISM IN QUESTION 4:

☐ You are or have been member of the Steering Committee
☐ You are or have been member of a working group of the mechanism
☐ You have attended some of the meetings of the mechanism
☐ You have provided advice as technical expert to the activities of the mechanism
☐ You work or collaborate with the secretariat of the mechanism

C. Gaps and challenges; success factors and barriers

13. Please, rate your opinion about the adequacy of the various inputs and processes that have served the Member State mechanism.

	(1) Extremely inadequate	(2) Inadequate	(3) Neutral	(4) Adequate	(5) Highly adequate	(–) Don't know
The explicit goals and objectives of the mechanism	☐	☐	☐	☐	☐	☐
The governance structure	☐	☐	☐	☐	☐	☐
The composition of the Steering Committee	☐	☐	☐	☐	☐	☐
The work-procedures of the mechanism	☐	☐	☐	☐	☐	☐
The priority areas of work	☐	☐	☐	☐	☐	☐
The effectiveness of meetings	☐	☐	☐	☐	☐	☐
The effectiveness of the working groups	☐	☐	☐	☐	☐	☐
The technical expertise of the members of the working groups	☐	☐	☐	☐	☐	☐
The technical expertise of external advisers or consultants	☐	☐	☐	☐	☐	☐
The extent and quality of the communication exchanged through the mechanism	☐	☐	☐	☐	☐	☐
The extent and quality of WHO communication and dissemination regarding products of the mechanism	☐	☐	☐	☐	☐	☐

	(1) Extremely inadequate	(2) Inadequate	(3) Neutral	(4) Adequate	(5) Highly adequate	(–) Don't know
The support provided by the Secretariat regarding communication and dissemination of products of the mechanism	☐	☐	☐	☐	☐	☐
The IT support provided by the Secretariat	☐	☐	☐	☐	☐	☐
The overall support provided by the Secretariat	☐	☐	☐	☐	☐	☐
The financial resources available for the mechanism	☐	☐	☐	☐	☐	☐

14. Which would you consider are the main success factors behind the achievements of the mechanism?

Please use the input field to type your answer.

_____

15. Which would you consider are the main barriers that hindered the progress of the mechanism?

Please use the input field to type your answer.

_____

16. Which would you consider are the best ways to communicate to national or regional regulatory authorities and other stakeholders about the Member State mechanism with a view to generate awareness and promote the use of its products?

Please use the input field to type your answer.

_____

17. To what extent would you consider the objectives of the mechanism have been reasonably addressed?

	(1) Not at all	(2) Poorly	(3) Somewhat	(4) Well	(5) Very well	(–) Don't know
Objective 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	☐	☐	☐	☐	☐	☐
Objective 2. To strengthen national and regional capacities in order to ensure the integrity of the supply chain	☐	☐	☐	☐	☐	☐
Objective 3. To exchange experiences, lessons learned, best practices, and information on ongoing activities at national, regional and global levels	☐	☐	☐	☐	☐	☐
Objective 4. To identify actions, activities and behaviours that result in SSFFC medical products and make recommendations, including for improving the quality, safety and efficacy of medical products	☐	☐	☐	☐	☐	☐
Objective 5. To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries	☐	☐	☐	☐	☐	☐
Objective 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 medical products	☐	☐	☐	☐	☐	☐
Objective 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	☐	☐	☐	☐	☐	☐
Objective 8. To promote cooperation and collaboration on surveillance and monitoring of SSFFC medical products	☐	☐	☐	☐	☐	☐
Objective 9. To further develop definitions of SSFFC medical products that focus on the protection of public health	☐	☐	☐	☐	☐	☐

D. Overall appraisal

18. What is your level of satisfaction with the work produced by the mechanism since its establishment in 2012?

□ (1) Very dissatisfied □ (2) Dissatisfied □ (3) Neutral □ (4) Satisfied □ (5) Very satisfied □ (–) Don't know

If you want to further elaborate regarding this question, please use the text field below:

_____

19. Would you consider the mechanism should continue beyond its first four years of operations?

□ Yes
□ Yes, with a few adjustments
□ Yes, but only with major adjustments
□ No
□ Don't know

If you want to further elaborate regarding this question, please use the text field below:

_____

FILTER OFF: ALL RESPONDENTS

20. To what degree does the work of the Member State mechanism have a positive or beneficial effect?

	(1) Not at all	(2) To a minor extent	(3) To a moderate extent	(4) To a large extent	(5) To a very large extent	(–) Don't know
…for your institution?	☐	☐	☐	☐	☐	☐
…for your country?	☐	☐	☐	☐	☐	☐
…at regional or global level?	☐	☐	☐	☐	☐	☐

21. In your opinion, which are the main issues facing your country in effectively promoting the prevention, detection and response to SSFFC medical products from a public health perspective?

Please use the input field to type your answer.

_____

22. In your opinion, which should be the priorities that WHO and the international community should undertake to address the prevention, detection and response to SSFFC medical products?

Please use the input field to type your answer.

_____

23. Is there anything else that you would like to add?

Please use the input field to type your answer.

_____

Thank you for responding to this survey.

If you are willing to be contacted to provide further feedback to the evaluation team, please indicate your name, affiliation and email address below. Your responses will remain private and confidential. If you do not wish to share your contact details, just leave the fields blank.

Please <u>click the submit-button</u> below to finalize the questionnaire.

Name: _____

Institution: _____

Mail address: _____

Submit.

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