

Member State mechanism on substandard and falsified medical products

Report by the Director-General

The Director-General has the honour to transmit to the Executive Board at its 144th session the reports of the sixth and seventh meetings of the Member State mechanism on substandard and falsified medical products (see Annexes 1 and 2), which met in Geneva from 30 November to 1 December 2017 and from 29 to 30 November 2018, respectively.¹

¹ The goal, objectives and terms of reference for meetings of the Member State mechanism were established in the Annex to resolution WHA65.19 (2012).

ANNEX 1

REPORT OF THE SIXTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS

1. The sixth meeting of the Member State mechanism on substandard and falsified medical products was held in Geneva on 30 November–1 December 2017, and was chaired by Dr Belén Escribano Romero of Spain, with the following Vice-Chairpersons: Dr Atany Bernardin Nyansa (Togo); Dr Catherine Sanga on behalf of Mr Hiiti Sillo (United Republic of Tanzania); Ms Camilla Horta Gomes on behalf of Ms Patricia Pereira Tagliari (Brazil); Ms Mary Lou Valdez (United States of America); Mr Tofigh Sedigh Mostahkam on behalf of Dr Rassoul Dinarvand (Islamic Republic of Iran); Mr Alastair Jeffrey (United Kingdom of Great Britain and Northern Ireland); Dr V.G. Somani (India); Ms Tika Wihanasari Tahar (Indonesia); Mr Liu Jingqi (China); and Mr Ann Ling Tan on behalf of Dr Salmah Bahri (Malaysia).¹ The session was attended by representatives of 45 Member States and one regional economic integration organization.

Update by the Secretariat on the activities and budget to implement the workplan of the Member State mechanism

2. The Secretariat provided an update on the activities and budget to implement the 2016–2017 workplan, including on the WHO Global Surveillance and Monitoring System, global medical product alerts, the smartphone application pilot study, regulatory strengthening and capacity-building activities, and the launch by the WHO Director-General on 29 November 2017 of two reports: *WHO Global Surveillance and Monitoring System for substandard and falsified medical products* and *A study on the public health and socioeconomic impact of substandard and falsified medical products*. Member States welcomed the linkage of the WHO Global Surveillance and Monitoring System to the Ibero-American regional system, FALFRA. Member States agreed that there was a need to ensure the financial sustainability of the Member State mechanism.

Update on implementation of the agreed list of prioritized activities for 2016–2017

Activity A

3. An informal meeting of the working group on Activity A had been convened by Brazil on 28 November 2017. The working group had revised the *Recommendations for health authorities on criteria for risk assessment and prioritization of cases of unregistered/unlicensed, substandard and falsified medical products*, and it had agreed that the document would be translated and published on the WHO website and shared on the MedNet platform. The Member State mechanism noted the executive summary of that document, as contained in document A/MSM/6/3 and attached as Annex 1. Brazil also provided an update on the working group's activities, including a summary of results from the survey on expertise and training, from which a handbook had been developed and which would be shared on the MedNet platform. It was agreed that Activity A should be included in the list of prioritized activities for the period for 2018–2019, and Member States were encouraged to nominate experts to join the working group.

¹ Mr Khalid Atlassi (Morocco) was unable to attend the meeting.

Activity B

4. The Secretariat provided an update on its activities towards expanding the global network of focal points and indicated that Member States would be reminded before the end of 2017 to nominate focal points. It was agreed that the Secretariat should work with the WHO regional and country offices, as well as the Missions in Geneva, to facilitate responses. Member States expressed support for efforts aimed at encouraging nominations within their respective regions.

Activity C

5. An informal technical session on Activity C had been convened by the Secretariat on 28 November 2017. Member States noted that the information on experiences in countries, previously set out in the document on existing technologies and “track and trace” models in use and to be developed by Member States,¹ had been updated with the results of the questionnaire on “track and trace” systems for human medicines sent out by the International Coalition of Medicines Regulatory Authorities (ICMRA), and that the updated table had been made available on the MedNet platform. Three presentations were given by representatives of ICMRA, the United States Pharmacopoeial Convention (USP) and Oxford University. Those organizations were encouraged to continue their work. Member States agreed that the working group should continue its work and that Activity C should be included as a prioritized activity in 2018–2019, with the methods of further work to be discussed.

Activity D

6. The Secretariat explained that discussion was under way related to the subject matter of Activity D and that there were other papers in development, notably the paper on access to medicines and vaccines that would be presented to the Executive Board at its 142nd session in January 2018. In that regard, the activity would be further discussed at the first Steering Committee meeting in 2018.

Activity E

7. The representative of the United Kingdom of Great Britain and Northern Ireland provided an update on the working group’s activities, including on the insights and implications from the global communications survey and next steps in developing standards and guidance to support Member State initiatives. Member States welcomed the announcement on funding from the United Kingdom to support the work of the working group. It was agreed that Activity E should be included in the list of prioritized activities for the period for 2018–2019.

Activity F

8. The Secretariat shared updates on the events to launch the two reports. A study on the public health and socioeconomic impact of substandard and falsified medical products and WHO Global Surveillance and Monitoring System for substandard and falsified medical products, including the press conference held on 28 November 2017 and the panel discussion opened by the WHO Director-General.

¹ Document A69/41, Appendix 2.

Activity G

9. The representative of the Office of the Legal Counsel clarified that, in accordance with resolution WHA65.19 (2012), the Member State mechanism was now required to report to the Health Assembly, through the Executive Board, on progress and any recommendations every two years. Consequently, the next comprehensive report would be submitted to the Seventy-second Health Assembly in May 2019 and would include the reports of both the sixth and seventh meetings of the Member State mechanism.

10. The Secretariat also informed the Member State mechanism that there was currently no funding gap to complete work on the prioritized activities for the 2016–2017 workplan, as well as for 2018–2019, subject to any new activities identified under the new prioritized workplan.

Activity H

11. Member States welcomed the wide and positive press coverage on the agreed definitions, following the decision taken by the Seventieth World Health Assembly.

Draft list of prioritized activities to implement the workplan of the Member State mechanism for the period 2018–2019

12. The Member State mechanism considered the draft list of prioritized activities for the period 2018–2019 submitted by the Steering Committee. In addition to five activities from the 2016–2017 workplan (Activities A–E), which remained in progress, the Member State mechanism would undertake three new activities (Activities F–H). While Activity H was focused on sales, distribution or supply of substandard and falsified medical products through the internet, there was discussion about concerns with regard to sales, distribution or supply through other media platforms. The prioritized activities are attached as Annex 2.

WHO's participation in the Global Steering Committee for Quality Assurance of Health Products

13. The Secretariat provided an update on WHO's participation in the Global Steering Committee for Quality Assurance of Health Products. The Member State mechanism supported inviting a representative of the Global Steering Committee to the next meeting of the mechanism's Steering Committee. Member States also requested a summary of the next Global Steering Committee meeting, in which WHO would continue to participate as a provisional observer.

Update on WHO's activities for regulatory systems strengthening, and on the application of WHO's global benchmarking tool

14. The Secretariat provided an update on WHO's work on strengthening regulatory systems for medical products, including the indicators related to substandard and falsified medical products. The draft global benchmarking tool was expected to be shared with Member States for consultation by December 2017, with the aim of publishing the global benchmarking tool and guidance manual in the first quarter of 2018. It was agreed that there would be a half-day, WHO-led technical session on regulatory systems strengthening at the next meeting of the Member State mechanism. An overview of the opportunities for strengthening of Member States' regulatory systems by WHO might be shared in the form of a document.

Proposed date of the seventh meeting of the Member State mechanism

15. The Member State mechanism decided that its seventh meeting would take place in the week of 26–30 November 2018.

Appendix

**DRAFT LIST OF PRIORITIZED ACTIVITIES TO IMPLEMENT THE WORKPLAN
OF THE MEMBER STATE MECHANISM FOR THE PERIOD 2018–2019**

Prioritized activities	Status	Actions
<p>A. Develop and promote training material and guidance documents to strengthen the capacity of national/regional regulatory authorities for the prevention and detection of and response to substandard and falsified medical products.</p> <p>Lead: Brazil (maintain working group)</p>	In progress	<ol style="list-style-type: none"> 1. Develop a guidance document on criteria for risk classification and assessment prioritization of cases of substandard and falsified medical products. 2. Assist in the identification of existing expertise and training material from Member States and other institutions concerning the prevention and detection of and response to substandard and falsified medical products. 3. Assist in the identification of training needs of different national/regional regulatory authorities. 4. Develop recommendations regarding national registers of manufacturers, importers, distributors and medical products authorized by Member States. 5. Develop training material for national/regional regulatory authorities, focused on promoting the technical documentation approved by the Member State mechanism. 6. Develop guidance documents to strengthen capacities of national/regional regulatory authorities for better prevention and better detection of, and more effective response to, substandard and falsified medical products.
<p>B. Expand and maintain the global focal point network among national medicines regulatory authorities to facilitate cooperation and collaboration.</p> <p>Lead: Secretariat</p>	In progress	<ol style="list-style-type: none"> 1. Continue to follow up with Member States to nominate focal points. 2. Continue to train new focal points and provide refresher training for existing focal points. 3. Facilitate the exchange of information in the global focal point network.

Prioritized activities	Status	Actions
<p>C. Improve Member States' understanding of detection technologies, methodologies and "track and trace" models.</p> <p>Lead: Argentina (working group reconvened) and the Secretariat</p>	In progress	<ol style="list-style-type: none"> 1. Convene open-ended expert sessions to review existing field detection devices and "track and trace" models and, as needed: <ol style="list-style-type: none"> (a) Provide updates on existing "track and trace" technologies in use by Member States; (b) Report on existing field detection devices in use or available to Member States; (c) Provide updates on existing available authentication technologies. 2. Working group to refine and present for approval a workplan for 2018–2019 through the Steering Committee as appropriate.
<p>D. Increase Member States' knowledge of the links between substandard and falsified medical products and access to quality, safe, efficacious and affordable medical products.</p> <p>Lead: Secretariat</p>	In progress	<ol style="list-style-type: none"> 1. Secretariat to review and report on future WHO activities on access to quality, safe, efficacious and affordable medical products from the angle of links with substandard and falsified medical products.
<p>E. Develop and leverage existing activity for effective risk communication and make recommendations for awareness campaigns on substandard and falsified medical products.</p> <p>Lead: United Kingdom of Great Britain and Northern Ireland (maintain working group)</p>	In progress	<ol style="list-style-type: none"> 1. Develop or leverage recommendations for effective risk communication and awareness campaigns. 2. Produce samples of hard and soft copy material and video and broadcast material. 3. Assess the use of social media for raising awareness. 4. Identify full range of stakeholders and audiences. 5. Develop key and innovative advocacy material.
<p>F. Enhance Member States' capacity to expand awareness, effectiveness, impact and outreach in their work on substandard and falsified medical products.</p> <p>Lead: Secretariat</p>	New activity	<ol style="list-style-type: none"> 1. Secretariat, working with Member States, to develop a workplan for the Secretariat and Member States to disseminate and promote the materials and information developed by the Member State mechanism. 2. Member States to use documentation developed by the Member State mechanism and WHO reports as tools to increase political awareness and advocacy at the highest policy levels about the need to support and dedicate resources to prevent, detect and respond to substandard and falsified medical products.

Prioritized activities	Status	Actions
G. Promote shared understanding among Member States from a public health perspective regarding medical products in transit.	New activity	1. Secretariat to provide an information note on the current situation regarding medical products in transit, within the public health domain.
Lead: Secretariat		
H. Identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet.	New activity	1. Establish a working group to: <ol style="list-style-type: none"> <li data-bbox="831 658 1182 687">(a) Develop terms of reference; <li data-bbox="831 696 1342 846">(b) Provide a problem statement identifying the range of issues that facilitate the sale and supply of substandard and falsified medical products through the internet both nationally and across borders; <li data-bbox="831 855 1334 1008">(c) Identify experiences or regulation of the distribution or supply of medical products via the internet to prevent and reduce the risk of substandard and falsified medical products reaching consumers; <li data-bbox="831 1016 1342 1169">(d) Develop guidance on strategies to enable national/regional regulatory authorities to address the distribution or supply of substandard and falsified medical products via the internet.
Lead: United Kingdom of Great Britain and Northern Ireland (pending confirmation) and Colombia (confirmed)		

ANNEX 2

REPORT OF THE SEVENTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS

1. The seventh meeting of the Member State mechanism on substandard and falsified medical products was held in Geneva on 29 and 30 November 2018 and was chaired by Dr Belén Escribano Romero (Spain), with the following Vice-Chairpersons: Mr Emmanuel Alphonse Nkiligi on behalf of Ms Agnes Kijo (United Republic of Tanzania); Dr Atany Bernadin Nyansa (Togo); Dr Varley Dias Sousa on behalf of Ms Patrícia Pereira Tagliari (Brazil); Ms Mary Lou Valdez (United States of America); Mr Tofigh Sedigh Mostahkam on behalf of Dr Abdol Majid Cheraghali (Islamic Republic of Iran); Mr Mohamed Amine Boukhris (Morocco); Mr Alastair Jeffrey (United Kingdom of Great Britain and Northern Ireland); Dr V. G. Somani (India); Ms Tika Wihanasari Tahar (Indonesia); Mr Liu Jingqi (China); and Dr Ramli Zainal (Malaysia). The meeting was attended by representatives of 53 Member States and one regional economic integration organization.

2. The Secretariat provided an update on the activities and budget to implement the mechanism's workplan, including on the WHO Global Surveillance and Monitoring System, regulatory systems strengthening and capacity-building activities. A general overview briefing of the Member State mechanism was completed on 28 November 2018. It was noted that a broader overview of donor support for activities related to substandard and falsified medical products would be made available at the eighth meeting of the Member State mechanism.

Update on implementation of the workplan and agreed list of prioritized activities for 2018–2019

Activity A

3. Brazil, as Chair of the working group, provided an update on Activity A. The Guidance for registers of manufacturers, importers, distributors and medical products authorized by Member States and its annex, and Recommendations for health authorities on criteria for risk assessment and prioritization of cases of unregistered/unlicensed, substandard and falsified medical products had been shared with Member States before the seventh meeting of the Member State mechanism and would be published on the MedNet platform and the WHO website. It was agreed that the Handbook on existing training resources and reference documentation for the prevention, detection and response to SF medical products and Guidance for registers of manufacturers, importers, distributors and medical products authorized by Member States and its annex should be considered living documents, updated by the Secretariat as needed and made widely available. The working group noted that it was open to receiving new members and suggestions for future activities. Any Member States interested in joining the working group were encouraged to contact the Secretariat.

Activity B

4. The Secretariat provided an update on its activities to expand the global network of focal points and Member States acknowledged the progress made. There were calls for the updates and the nomination process for focal points to be simplified; the Secretariat would explore practical ways to encourage additional nominations, if necessary. Member States again underscored the value of joining

the Global Focal Point Network and of incentives to encourage continued active participation, including by sharing the technical documents and other outputs of the Member State mechanism.

Activity C

5. The Secretariat provided an update on three strands of work: detection technologies, including the work of the University of Oxford and the United States Pharmacopeial Convention; “track and trace” models and experiences from Member States; and the lessons learned and best practices from the smartphone application pilot studies in the United Republic of Tanzania and in Indonesia. All reviews of detection technologies published by the University of Oxford and the United States Pharmacopeial Convention had been posted on the MedNet platform and the WHO website. It was noted that an exchange of information on those issues was critical. Likewise, it was important to share the key lessons learned from such activities with Member States, including the findings of the smartphone application pilot studies. It was confirmed that Argentina would be unable to continue to co-lead the activity. The Member States therefore agreed that the Secretariat would continue in that role and report on progress until a new Member State co-lead was identified. Any Member States interested in leading this activity were encouraged to notify the Secretariat.

Activity D

6. The Secretariat provided an update on the development of the road map on access to medicines and vaccines 2019–2023, requested by the World Health Assembly in decision WHA71(8) (2018), which included improved prevention, detection, and response to substandard and falsified medical products. The draft road map would be submitted to the Seventy-second World Health Assembly through the 144th session of the Executive Board. For potential future publications on linkages between access to safe, quality, efficacious and affordable medical products and substandard and falsified medical products, it was resolved that key emerging themes for further research would be discussed with the Steering Committee.

Activity E

7. A demonstration workshop had been convened on 28 November 2018 by the United Kingdom of Great Britain and Northern Ireland. As Chair of the working group, the United Kingdom provided an update on Activity E. The IDEAS (insight, data, engagement, action and solutions) framework for substandard and falsified medical products global communications guidance and Assessing the value of social media for raising awareness of SF medical products documents as well as the curation and collection of communication campaign materials from Member States would be published on the MedNet platform and the WHO website; and it was encouraged to widely disseminate those documents via other platforms. The Secretariat would monitor the use of the handbook identify best practices and areas for development and bring these back to the Member State mechanism. While it was noted that the United Kingdom of Great Britain and Northern Ireland would no longer be able to chair the working group, Member States underscored the value of communications work. Any Member States interested in leading Activity E were encouraged to notify the Secretariat.

Activity F

8. The Secretariat provided an update on the policy, technical and advocacy coverage in all WHO regions of the work of the Member State mechanism. Relevant communications and outreach material would be added on the MedNet platform, including overview presentations, relevant speeches by the Director-General and key messages, to help ensure consistent messaging. In addition, all translated

versions of the mechanism's technical documents would be uploaded to the WHO website, to ensure ease of reference. It was noted that a calendar of events should be made available and updated on MedNet, and Member States were encouraged to identify, share and participate in relevant opportunities around increased outreach and awareness.

Activity G

9. In its update on Activity G, the Secretariat said that a discussion paper on transit, including a questionnaire and responses from 26 focal points from the African Region, had been shared with Member States before the seventh meeting of the Member State mechanism. It had been agreed that interested Member States would work together to enhance knowledge of transit issues, as well as to facilitate more meaningful engagement between relevant customs and health authorities, including by redesigning the questionnaire. The following Member States had agreed to work with the Secretariat: Ireland, Malaysia, Nigeria, Spain, the United Republic of Tanzania and Zambia. Other Member States interested in participating in Activity G were encouraged to contact the Secretariat.

Activity H

10. A technical session had been convened on 27 November 2018 by Colombia; as Chair of the working group, Colombia provided an update on Activity H. The working group's terms of reference had been shared with Member States before the seventh meeting of the Member State mechanism. It was noted that feedback from Member States during the technical session would also inform the development of documents included in the scope of the activity. Member States that had not already done so were encouraged to respond electronically to the web questionnaire circulated via MedNet on the distribution or supply of substandard or falsified medical products on the Internet. Any other Member States interested in joining the working group were encouraged to contact the Secretariat.

11. While the scope of Activity H would maintain its focus on the Internet, there was discussion about concerns with regard to the sale, distribution or supply of substandard or falsified medical products through other platforms, such as television, radio and other means of mass communication. It was noted that further discussions could take place at the eighth meeting of the Member State mechanism, during the discussion around the development of new prioritized activities.

WHO's participation in the Global Steering Committee for Quality Assurance of Health Products

12. The Secretariat provided an update on WHO's participation in the Global Steering Committee for Quality Assurance of Health Products, in which WHO participated as an observer on a provisional basis, adding that a representative of the Global Steering Committee had given a presentation at the meeting of the mechanism's Steering Committee on 3 and 4 October 2018.

13. It was agreed that, at future meetings of the Member State mechanism and its Steering Committee, the scope of the agenda item should be broadened so as to enable the Secretariat to provide information, as appropriate and necessary, on other global and regional initiatives relating to substandard and falsified medical products. The Secretariat was encouraged to share/exchange information, align any relevant tools and use information from such initiatives and the Member State mechanism.

Update on WHO activities for regulatory systems strengthening

14. At a technical session convened on 28 November, the Secretariat had provided an update on WHO work to strengthen regulatory systems for medical products. During the plenary session, Member States were updated on the progress made on those activities, including the alignment of substandard and falsified medical products within the WHO Global Benchmarking Tool. The Secretariat was requested to publish the programmes which are available from WHO for regulatory systems strengthening.

Update on governance issues

15. The representative of the Office of the Legal Counsel reminded Member States that, in accordance with resolution WHA65.19 (2012), the Member State mechanism was required to report to the Health Assembly, through the Executive Board, on progress and any recommendations annually for the first three years, and every two years thereafter. Accordingly, the Member State mechanism would submit its next report to the Seventy-second World Health Assembly in May 2019. The document would consist of the reports of both the sixth and the seventh meetings of the Member State mechanism. The Secretariat informed the Member States that the technical documents produced by the working groups would be available on the WHO website and that links to those documents would be included in the report submitted to the Seventy-second World Health Assembly.

16. The Member States noted that the new composition of the Steering Committee, beginning from the closure of the seventh meeting of the Member State mechanism, would be as follows:

- African Region: Benin and Kenya
- Region of the Americas: Brazil and the United States of America
- Eastern Mediterranean Region: Islamic Republic of Iran
- European Region: Russian Federation and Spain
- South-East Asia Region: India and Indonesia
- Western Pacific Region: China and Malaysia

17. It was noted that Member States would be informed of the appointment of the second Vice-Chairperson from the Eastern Mediterranean Region, once it had been confirmed.

18. As recommended by the Health Assembly in decision WHA66(10) (2013) and agreed by the Member State mechanism, the chairmanship rotated among the six WHO regions, in English alphabetical order. The next Chairperson would therefore come from the South-East Asia Region. When that appointment was confirmed, the Member States would be notified.

Proposed dates of the eighth meeting of the Member State mechanism

19. The Member State mechanism decided that its eighth meeting would take place in the week of 21 October 2019.

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