



**World Health
Organization**

**EXECUTIVE BOARD
148th session
Provisional agenda item 10**

**EB148/12
23 December 2020**

Substandard and falsified medical products

Report by the Director-General

The Director-General has the honour to transmit to the Executive Board at its 148th session the reports of the eighth and ninth meetings of the Member State mechanism on substandard and falsified medical products (see Annexes 1 and 2), which met in Geneva from 24 to 25 October 2019 and virtually from 28 to 29 October 2020, 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 EIGHTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS

1. The eighth meeting of the Member State mechanism on substandard and falsified medical products was held in Geneva on 24 and 25 October 2019, and was chaired by Dr V.G. Somani (India), with the following Vice-Chairpersons:¹ Mr Oluwkyodé Nils Daniel Kintin (Benin); Mr Wilberforce Kariuki Gachoki (Kenya); Ms Bianca Zimon Giacomini Ribeiro on behalf of Mr João Paulo Ortega Terra (Brazil); Ms Mary Lou Valdez (United States of America); Ms Yasmine Jamal Ameen Kannan (Iraq); Mr Manuel Ibarra Lorente (Spain); Mr Sergey V. Glagolev (Russian Federation); Ms Meutia Hasan (Indonesia); Mr Liu Jingqi (China); and Dr Ramli Zainal (Malaysia). The meeting was attended by representatives of 52 Member States and one regional economic integration organization.

2. The WHO Director-General opened the meeting and reiterated his support for the WHO Member State mechanism as the forum for developing global approaches to the prevention and detection of, and response to, substandard and falsified medical products.

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

3. The Secretariat provided an update on the activities and budget (including grants and proposals) to implement the mechanism's workplan, including on the WHO transformation agenda, the WHO Global Surveillance and Monitoring System, medicine quality surveys, and WHO global medical product alerts. It was noted that the data emerging from the various sources would be useful in guiding the work of the mechanism and should be made accessible to Member States, including through publications. Concerning medicine quality surveys, the importance to Member States of receiving that data as soon as possible was noted.

4. In line with the WHO transformation agenda and the Thirteenth General Programme of Work, 2019–2023, WHO would prioritize work based on country needs, including those identified as WHO global public health goods and requests included in country support plans as developed by ministries of health, in coordination with WHO country and regional offices.

5. The Member State mechanism requested WHO to ensure continuity of support to strengthen the Secretariat substandard and falsified medical products group as it was important for the workplan.

¹ Dr Abdol Majid Cheraghali (Islamic Republic of Iran) was unable to attend the meeting.

Update on the list of prioritized activities for 2018–2019

Activity 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

6. Brazil, as Chair of the working group, provided an update on Activity A. Following discussions with the Steering Committee, a new action on risk-based post-market surveillance was proposed, containing two distinct but complementary approaches (as described in the Appendix). It was agreed that the development of the tool should be chaired by the Secretariat and a parallel technical working group chaired by Brazil should be established to develop the guidance. An informal background document on risk-based post-market surveillance had been shared with Member States via MedNet before the eighth meeting of the Member State mechanism.

7. For the new action proposed on risk-based post-market surveillance to be led by Brazil, a working group of Member States would be formed, with next steps to include the development of terms of reference for the working group on guidance. Any Member State interested in joining that working group on the development of guidance on risk-based post-market surveillance was encouraged to contact the Secretariat as soon as possible. The following Member States had already expressed an interest in doing so: Algeria, Angola, Colombia, Guinea, India, Indonesia, Kenya, Mozambique, Nigeria, the United Kingdom of Great Britain and Northern Ireland, the United Republic of Tanzania and the United States of America.

8. An informal technical meeting of the risk-based post-market surveillance technical working group of experts developing the survey tool chaired by the Secretariat had been convened on 21 October 2019. The meeting had been attended by representatives of Algeria, Brazil, India, Indonesia, Nigeria, Spain, the United Republic of Tanzania, the United States of America, and experts from Oxford University, the University of North Carolina and the United States Pharmacopeial Convention. The terms of reference for the working group on tools had been agreed upon and would be circulated by the Secretariat on MedNet. The tool and guidance would be piloted in the United Republic of Tanzania. Progress would be reported to the Steering Committee, with the final report being shared with Member States during the ninth meeting of the Member State mechanism.

Activity B: Expand and maintain the Global Focal Point Network among national medicines regulatory authorities to facilitate cooperation and collaboration

9. The Secretariat provided an update on its activities to maintain the global network of focal points. The value of active participation in the Global Focal Point Network was underscored, including the importance of having the support of the heads of national medicines regulatory authorities in reporting to the WHO Global Surveillance and Monitoring System. In line with the agreed terms of reference for the Global Focal Point Network, the Secretariat noted that the list and contact information would require regular updating and that all Member States would be contacted to ensure that the list was up-to-date. Member States were also reminded to communicate any changes to the Secretariat. Members of the Global Focal Point Network were encouraged to interact with each other in order to fulfil the objectives of the mechanism.

Activity C: Improve Member States' understanding of detection technologies, methodologies and "track and trace" models

10. The Secretariat provided an update on three strands of work under Activity C: traceability of health products,¹ the smartphone application reporting project, and field detection and screening technologies and devices. The draft policy brief on traceability of health products and the pilot study report on the smartphone application for reporting substandard and falsified medical products had been shared with Member States via MedNet before the eighth meeting of the Member State mechanism. Member States interested in leading Activity C were encouraged to notify the Secretariat.

11. An informal technical meeting on traceability of health products had been convened by the Secretariat on 22 October 2019. The Secretariat reported that the draft policy brief would undergo additional consultation, and comments would be welcomed from Member States. Transparency in the feedback received was encouraged, with the understanding that confidentiality would need to be considered if requested. A final version of the policy brief would be submitted to the ninth meeting of the Member State mechanism, and, for the benefit of all, would be made available by WHO as a draft until it had been finalized and adopted.

12. In respect of the smartphone reporting application project, it was noted that the pilot study report had been completed and would be published, with additional insights on the impact of the type and settings of health facilities. Member States welcomed the project's expansion to include additional countries, reiterating the importance of integrating sustainability in WHO's request for proposals soon to be issued.

13. An informal technical meeting on detection and screening technologies had been convened by the Secretariat on 23 October 2019. The Secretariat reported on the ongoing work of Oxford University, the United States Pharmacopeial Convention and WHO. Member States welcomed the continued coordination of such activities.

Activity D: Increase Member States' knowledge of the links between substandard and falsified medical products and access to quality, safe, efficacious and affordable medical products

14. The Secretariat provided an update on the emerging links between access to medicines and substandard and falsified medical products, using the data collected and analysed from the WHO Global Surveillance and Monitoring System. A draft document had been prepared that would benefit from scientific validation. Member States supported the alignment with the WHO road map on access to medicines and vaccines 2019–2023, which included the prevention and detection of, and response to, substandard and falsified medical products, and noted the need for a more in-depth assessment of the impact of that issue on the affordability, availability and acceptability of medical products. Member States encouraged the Secretariat to report progress to the Steering Committee.

¹ Health products include finished medicines, including vaccines and pharmaceuticals.

Activity E: Develop and leverage existing activity for effective risk communication and make recommendations for awareness campaigns on substandard and falsified medical products

15. The Secretariat provided an update on the country insight studies, aligned to the IDEAS (Insight, Data, Engagement, Action and Solutions) global communications campaign framework to help combat the threat of substandard and falsified medical products under way in four Member States (Ghana, Nigeria, Sierra Leone and Uganda). The other deliverables/actions (1 to 5) under Activity E would be based on the results of those studies. An update was also provided on the progress of the pharmacy school project under way in five Member States (Cameroon, Nigeria, Senegal, Uganda and the United Republic of Tanzania). The value of increasing education and awareness, one of the key pillars of preventing substandard and falsified medical products, was emphasized. Member States interested in leading Activity E were encouraged to notify the Secretariat.

Activity F: Enhance Member States' capacity to expand awareness, effectiveness, impact and outreach in their work on substandard and falsified medical products

16. The Secretariat provided an update on the policy and technical coverage of the Member State mechanism's work in all WHO regions, including the drafting of an advocacy document which would be updated with the agreed prioritized activities so as to implement the workplan of the Member State mechanism for the period 2020–2021. The document would be made available in all United Nations languages and published in hard copy and online. Member States interested in leading Activity F were encouraged to notify the Secretariat.

Activity G: Promote shared understanding among Member States from a public health perspective regarding medical products in transit

17. The Secretariat provided an update on medicines in transit. A technical working group had been convened, and a questionnaire had been established, translated into six languages and circulated to the Global Focal Point Network. Responses to the survey had been requested by 5 November 2019, with the aim of reporting progress and results to the Steering Committee. The Member State mechanism had requested the Secretariat to circulate the results to the members of the mechanism. Member States interested in leading Activity G were encouraged to notify the Secretariat.

Activity H: Identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet

18. Colombia, as Chair of the working group, provided an update on Activity H. An informal technical meeting on the internet had been convened by Colombia on 22 October 2019. A problem statement identifying the range of issues that facilitated the sale and supply of substandard and falsified medical products through the internet both nationally and across borders had been published as an official document before the eighth meeting of the Member State mechanism. As next steps to completing an assessment of the experiences of national medicine regulatory authorities (action 1(c)), a timeline had been agreed, and a drafting group of Member States (Brazil, India, Indonesia, Ireland, Malaysia, Nigeria, Spain, the United Republic of Tanzania and the United States of America) formed to develop and disseminate a survey to the Global Focal Point Network and the members of the mechanism.

19. An information session with internet platforms had been convened by the Secretariat on 23 October 2019. Member States expressed their appreciation for the information shared by the platforms and requested continued engagement by the mechanism with similar stakeholders, as appropriate.

WHO's participation in relevant global and regional initiatives

20. The Secretariat provided an update on WHO's engagement in relevant global and regional initiatives, highlighting areas of coordination with the Member State mechanism. The Secretariat was encouraged to continue to share information on the various initiatives via MedNet.

Draft list of prioritized activities to implement the workplan of the Member State mechanism for the period 2020–2021

21. Member States considered the draft list of prioritized activities for the period 2020–2021 submitted by the Steering Committee. The agreed list of prioritized activities for the period 2020–2021 is attached in the Appendix.

22. The members of the mechanism also acknowledged the proposal to compile a list of the various regional initiatives to tackle the issue of distribution and supply of substandard and falsified medical products via the internet and include it in Activity H, in coordination with the Secretariat.

23. Furthermore, as a potential future activity, Member States were supportive of holding informal discussions with interested Member States, facilitated by Italy, with a view to generating a scoping paper through the Steering Committee on the need to establish a similar network on medical devices, for consideration during the ninth meeting of the Member State mechanism.

Proposed dates of the ninth meeting of the Member State mechanism

24. The Member State mechanism decided that its ninth meeting would take place in the week of 26–30 October 2020.

Appendix

**AGREED LIST OF PRIORITIZED ACTIVITIES TO IMPLEMENT THE
WORKPLAN OF THE MEMBER STATE MECHANISM FOR
THE PERIOD 2020–2021**

Agreed 25 October 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 and Secretariat</p>	In progress	<ol style="list-style-type: none"> 1. Develop training material for national/regional regulatory authorities, focused on promoting the technical documentation approved by the Member State mechanism. 2. Assist in the identification of the training needs, existing expertise and training materials of Member States and other institutions in order to build capacity concerning the prevention and detection of, and response to, substandard and falsified medical products. 3. Risk-based post-market surveillance: <ol style="list-style-type: none"> (a) Develop tools and a database to automate the conduct of medical products quality surveys and enhance the quantity and quality of data captured to inform risk-based post-market surveillance programmes based on existing WHO guidance. (b) Develop guidance documents to strengthen capacities of national/regional regulatory authorities to plan, perform, and assess risk-based post-market surveillance including the effective use of the tools.
<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: 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" and authentication technologies in use by Member States; and (b) report on existing field detection devices in use or available to Member States. 2. Working group to continue to develop the policy paper on "track and trace" and submit a finalized document to the Member State mechanism.
<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: Secretariat</p>	In progress	<ol style="list-style-type: none"> 1. Conduct surveys on patient or consumer attitudes and behaviours on accessing medical products in four African countries, and <ol style="list-style-type: none"> (i) develop or leverage recommendations for effective risk communication and awareness campaigns; (ii) produce samples of hard and soft copy material and video and broadcast material; (iii) assess the use of social media for raising awareness; (iv) identify the full range of stakeholders and audiences; and (v) develop key and innovative advocacy material. 2. Pilot the implementation of a compulsory element in the pharmacy school curriculum in five African countries.
<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>	In progress	<ol style="list-style-type: none"> 1. Secretariat, working with Member States, to enable a proactive approach 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.	In progress	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.	In progress	1. A working group was established to: <ul style="list-style-type: none"> (a) develop terms of reference (completed); (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 (completed); (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; and (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: Colombia		

ANNEX 2

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

1. The ninth virtual meeting of the Member State mechanism on substandard and falsified medical products was held in Geneva on 28 and 29 October 2020 and was chaired by Dr V.G. Somani (India), with the following Vice-Chairpersons: Mr Oluwkyodé Nils Daniel Kintin (Benin); Mr Wilberforce Kariuki Gachoki (Kenya); Ms Laila Mouawad on behalf of Mr Leonardo Dutra Rosa (Brazil); Mr Mark Abdoo (United States of America); Dr Leila Mousavi (Islamic Republic of Iran); Ms Yasmine Jamal Ameen Kannan (Iraq); Mr Manuel Ibarra Lorente (Spain); Mr Sergey V. Glagolev (Russian Federation); Ms Ratna Irawati on behalf of Ms Meutia Hasan (Indonesia); Mr Liu Jingqi (China); and Mr Roeslan bin Ishak (Malaysia). The meeting was attended by representatives of 82 Member States.

2. The WHO Deputy Director-General opened the meeting and acknowledged the burden of substandard and falsified medical products as an unacceptable global public threat. Efforts to ensure access to safe, quality, affordable and effective medical products would be undermined if patients and end users received products that were substandard or falsified. She reiterated her support for the WHO Member State mechanism as a forum for developing global approaches to the prevention and detection of, and response to, substandard and falsified medical products.

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

3. The Secretariat provided an update on the activities and budget to implement the mechanism's workplan, including on the new incidents and substandard and falsified medical products team structure, information technology improvements to the WHO Global Surveillance and Monitoring System, WHO global medical product alerts, the medicine quality surveys, the post-market and market surveillance of medical devices, and the smartphone reporting application, as well as an update on the global situation of substandard and falsified medical products related to the coronavirus disease (COVID-19) pandemic. Member States reiterated the value of ensuring the sustainability of the Secretariat's work given its link to regulatory systems strengthening. They noted the update by the Secretariat on its activities and budget to implement the workplan of the Member State mechanism, as contained in document A/MSM/9/4.

Update on the list of prioritized activities for 2020–2021

4. The Steering Committee requested the Secretariat to update the plenary session on their recommendations and open discussion points for each prioritized activity within the workplan, including the possibility of creating dedicated working groups to address those points. Member States wishing to lead or join the prioritized activities and/or a working group were encouraged to contact the Secretariat. Member States noted the update on the list of prioritized activities for 2020–2021, as contained in document A/MSM/9/5.

Activity 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

5. The Secretariat provided an update on actions 1 and 2 under Activity A that focused on identifying training needs and developing capacity strengthening activities/material. Member States noted that such activities must match country needs to ensure effective knowledge transfer. Comments were made around ensuring impact and the possibility of developing a concept that detailed how training contributed to building regulatory capacity. Staff turnover was expressed as a challenge; the Train-the-Trainer approach – namely to have trained regulatory staff train others in their respective region – was noted as a means of ensuring sustainability in that regard. Member States agreed on the importance of taking a risk-based approach complemented with multistakeholder engagement to ensure practical implementation and widespread impact.

6. The Secretariat provided an update on action 3(a) regarding the risk-based post-market surveillance project. Innovative tools and approaches for risk-based post-market surveillance were being piloted in the United Republic of Tanzania. That work area comprised four different workstreams: an update of survey protocol, the development of IT tools (mobile application and database), the strengthening of laboratory capacity, and the conducting of a return on investment study that was expected to leverage support for national regulatory authorities.

7. Brazil, as Chair of the working group, provided an update on action 3(b) regarding the development of draft guidance on risk-based post-market surveillance, including a proposed framework and time frame of next steps with the final document to be submitted at the tenth meeting of the Member State mechanism. It was agreed that the Secretariat would issue a call for additional Member States to join the working group.

Activity B: Expand and maintain the Global Focal Point Network among national medicines regulatory authorities to facilitate cooperation and collaboration

8. The Secretariat provided an update on its activities to maintain the Global Network of Focal Points, including ongoing efforts to ensure that the focal point lists were current and up-to-date. Member States were reminded that the Global Focal Point Network was a distinct entity from, but worked in a complementary manner with the Member State mechanism, and close and regular communication should be maintained between the two bodies.

9. Member States noted that they had been able to use the Global Focal Point Network to share information during the COVID-19 pandemic and underscored the importance of the WHO Global Surveillance and Monitoring System – including the Global Focal Point Network – to maintaining strong links with regional networks and communities. In line with the agreed terms of reference for the Global Focal Point Network,¹ there was consensus that focal points should be empowered and encouraged to report substandard and falsified medical products as early as possible to the WHO Global Surveillance and Monitoring System, with any reporting barriers being removed. It was noted that a webinar on the roles and responsibilities of the Global Focal Point Network would be useful. The possibility of creating a dedicated working group to identify solutions to reporting barriers was discussed.

¹ Document A69/41, Appendix 1.

Activity C: Improve Member States' understanding of detection technologies, methodologies and "track and trace" models

10. The Secretariat provided an update on action 1 under Activity C, specifically the open-ended expert session that had taken place on 26 October 2020 to share the latest knowledge on the topic, which had included presentations by representatives from Oxford University, the United States Pharmacopeial Convention and WHO. Member States reiterated the value of such work in helping to inform selection, procurement and deployment decisions, and supported further open-ended expert sessions being held. It was agreed that the Secretariat should continue to promote evidence-based decision-making, including through additional reviews and assessments. The Secretariat reminded Member States that WHO did not promote nor advocate any product (neither technology format nor device). Member States discussed the need to continue such open-ended briefings, but noted that the objectives of each session should be better defined. Member States called for technical guidance from WHO in the area of detection technologies. It was noted that a dedicated working group would be required to define the scope and objectives of such guidance. Member States interested in joining that working group were encouraged to contact the Secretariat.

11. The Secretariat provided an update on action 2 concerning the traceability of health products and noted that the corresponding documents had been drafted with the support of 19 Member States. It was agreed that the technical traceability paper would become a WHO publication, with Annex 3 on country and regional experiences serving as a stand-alone document so that it could be updated more regularly. Member States agreed on the convening of open-ended expert sessions and noted the update by the Secretariat on Activity C, as contained in document A/MSM/9/3.

Activity D: Increase Member States' knowledge of the links between substandard and falsified medical products and access to quality, safe, efficacious and affordable medical products

12. The Secretariat summarized the report on the links between substandard and falsified medical products and access to medicines including for accessibility, affordability, availability and acceptability. Member States noted the report by the Secretariat on Activity D, as contained in document A/MSM/9/6, and agreed upon the recommendations outlined in paragraphs 19 and 20 of that report.

Activity E: Develop and leverage existing activity for effective risk communication and make recommendations for awareness campaigns on substandard and falsified medical products

13. The Secretariat provided an update on action 1 under Activity E regarding the insight studies and risk communication campaigns conducted in Ghana, Nigeria, Sierra Leone and Uganda, as well as the pharmacy school curriculum pilot with five universities in Cameroon, Nigeria, Senegal, the United Republic of Tanzania and Uganda. Once the operational work had been completed, the results would be published and shared in order to raise global and regional awareness and strengthen learning.

14. The Secretariat provided a further update on action 1 regarding the attitudinal and behavioural factors for, as well as the demographic groups at higher risk of, buying and/or using substandard and falsified medicines. The Secretariat continued to work with the national medicines regulatory authorities in the four countries involved in the insight studies in order to plan for and launch the evidence-based risk communication campaigns, including by developing practical evaluation models.

15. The Secretariat provided an update on action 2 regarding the pharmacy school curriculum pilot, describing the completion of virtual training and the sharing of teaching materials via an online resource platform. Despite the implementation delays owing to the COVID-19 pandemic, it was noted that the curriculum would be rolled out once universities resumed. Member States requested access to the post-pilot project expansion as well as to the training materials.

16. Member States further requested that the Secretariat provide reports on how both the risk communication campaigns and the pharmacy school pilot project had been developed and implemented, once those activities had been completed. Member States discussed the possibility of creating a dedicated working group to identify ways in which Member States and other relevant stakeholders could build on the lessons learned from such projects.

Activity F: Enhance Member States' capacity to expand awareness, effectiveness, impact and outreach in their work on substandard and falsified medical products

17. The Secretariat had taken a proactive approach to disseminating and promoting the work of the Member State mechanism, with the aim of supporting Member States to increase awareness and advocacy at the highest policy levels. The issue of substandard and falsified medical products had been recognized as an urgent global health challenge and a WHO health topic, with ongoing efforts to strengthen high-level advocacy, increase social media engagement, and develop resources (including an information booklet). Member States were encouraged to deploy those communication and advocacy products within their respective regional and national contexts. Member States discussed the possibility of creating a dedicated working group designed to link national, regional and global awareness-raising efforts.

18. Member States supported the idea of observing world health or regional health days on substandard and falsified medical products. The Secretariat recalled that the matter of world health days would be considered at the resumed session of the Seventy-third World Health Assembly. It was also noted that initiatives could be developed at the regional level. Member States committed to exploring that process and moving it forward in their respective regions.

Activity G: Promote shared understanding among Member States from a public health perspective regarding medical products in transit

19. The Secretariat provided an update on Activity G regarding medicines in transit, including the re-circulation of the questionnaire to the Global Focal Point Network. The results of the questionnaire would be used in the development of the information note on the current situation regarding medical products in transit within the public health domain. Member States were supportive of increasing coordination and collaboration with the World Customs Organization and noted the need to ensure a public health focus using the agreed substandard and falsified medical product definitions. In response to Member States' request, it was agreed that the submission deadline for the questionnaire would be extended until the end of January 2021 to allow more time for Member States to respond. Member States discussed the need to better define the application of the information resulting from the analysis of the questionnaire responses.

Activity H: Identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet

20. Colombia, as Chair of the working group, provided an update on Activity H, describing the development of the report on Member States' experiences or regulations, which had been compiled using the survey responses from the mechanism. The draft report would be shared with the mechanism for consultation before being finalized. The next step for the working group would be to develop guidance on strategies designed to enable national/regional regulatory authorities to address the issue.

21. The representative of Italy provided an update on the development of the online "good practices" bookshelf that was aimed at collecting and sharing existing good practices related to internet investigations. Such work complemented the efforts made in that area by the working group chaired by Colombia.

WHO's participation in relevant global and regional initiatives

22. The Secretariat provided an update on WHO engagement in relevant global and regional initiatives, highlighting the linkages with the Member State mechanism. The Member State mechanism supported WHO's continued engagement in those initiatives. To avoid duplication of work and ensure greater strategic coordination, wherever possible, it was agreed that both the Secretariat and Member States would engage in regional, cross-regional and global initiatives that would help to elevate the profile of the WHO Member State mechanism to the highest levels. Member States discussed the possibility of creating a dedicated working group aimed at coordinating input and strategic impact in such forums.

Update on governance issues

23. Responding to the request made by the Member State mechanism at its eighth meeting, the Secretariat provided an update on the progress made during the informal discussions with interested Member States on the drafting of a scoping paper and the need to establish a similar network on medical devices. Member States acknowledged that COVID-19 had highlighted the need for safe, quality and effective medical devices, in particular personal protective equipment. It was clarified that the working definitions for substandard, falsified and unregistered medical products endorsed by the Seventieth World Health Assembly provided that "a medical product is defined as a medicine, vaccine or in vitro diagnostic (...) and it may also include medical devices at an appropriate time in the future."¹ It was agreed that medical devices other than in vitro diagnostics fell outside the scope of the Member State mechanism at present, and it was decided that the Secretariat would convene with interested Member States to discuss how to take such work forward.²

24. Member States acknowledged that the Member State mechanism delegates changed often. It was agreed that a procedural document to assist Member States in better understanding and navigating the intergovernmental process (e.g. terms of reference and working processes) should be developed. It was agreed that the Secretariat would convene with interested Member States to discuss how to take that

¹ Document A70/23, Annex, Appendix 3, footnote 2.

² The representative of the United States of America expressed their reservation to this paragraph of the report.

work forward in collaboration with the Steering Committee. The draft report would be considered by the Steering Committee and submitted to the Member State mechanism.

25. It was noted that the terms of the current Steering Committee members had commenced at the closure of the seventh meeting of the Member State mechanism in 2018 and were set to expire at the closure of the ninth meeting of the Member State mechanism. It was further noted that the current list of prioritized activities covered the biennium 2020–2021 and that the next list of prioritized activities would be considered at the tenth meeting of the Member State mechanism in 2021.

26. The Member State mechanism agreed with the Steering Committee’s recommendation to align the terms of the current Steering Committee members with the time frame established for the application of the list of prioritized activities. Accordingly, the mechanism agreed to extend the terms of the current Chairperson and Vice-Chairpersons by one year, such that their terms would expire at the closure of the tenth Member State mechanism in 2021. It was understood that the subsequent terms of Chairpersons and Vice-Chairpersons would continue to expire at the closure of every second regular session of the Member State mechanism.

Proposed dates of the tenth meeting of the Member State mechanism

27. The Member State mechanism decided that its tenth meeting would take place in the week of 25–29 October 2021.

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