

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 Cammilla 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

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

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.

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.

¹ Document A69/41, Appendix 2.

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.

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.

ANNEX 1

RECOMMENDATIONS FOR HEALTH AUTHORITIES ON CRITERIA FOR RISK ASSESSMENT AND PRIORITIZATION OF CASES OF UNREGISTERED/UNLICENSED, SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS**EXECUTIVE SUMMARY¹**

1. Risk assessment is a process of assessing the potential severity of a risk event, based on the premise that not all of such events are equally important. The results of a risk assessment should be used to establish an importance ranking of alerts, notifications and reports received by regulatory authorities, based on the identification of cases with greater potential to cause damage to public health. Ranking the events based on their significance helps decision-makers in regulatory authorities to better understand where resources may be most needed, to reduce the timeframe to initiate actions and to establish a protocol of actions according to the severity of the case, in order to protect patients' health and safety. **This prioritization is especially important where the number of alerts, notifications and reports received by the regulatory authority exceed its capacity to act immediately in all cases.**
2. The use of a well-defined and simple procedure/tool to perform a risk assessment is desirable in order to obtain standardized and reliable results. The full document describes elements and criteria that may be considered in order to conduct a rapid risk assessment and prioritization of events involving unregistered/unlicensed, substandard and falsified medical products. It is a reference that regulatory authorities can customize or that they can use to create their own risk analysis and management procedure/tool, considering their regional/national reality.
3. The recommendation is that regulatory authorities always consider cases of falsified medical products as presenting a high risk, and investigate them immediately. Hence, a risk assessment tool to indicate priority levels is especially useful for the analysis of cases involving unregistered/unlicensed and substandard medical products.
4. Each regulatory authority should identify and select, based on its experience and data available, the factors to be considered for risk assessment. The full document suggests that the evaluation should include, at least to some degree, the following factors: severity of defect/non-compliance, potential clinical consequences, whether or not the product is of high potency or low therapeutic index, and the route of administration and place of action. In addition, other factors might be relevant in the action plan developed by regulatory authorities to define the next steps for a specific case. Such factors include the following: the probable place of the deviation; the exposed population; the frequency of occurrence; market turnover and expiration date; whether or not the product is the single medical product on the market or used in national/international health care programmes; and the degree of

¹ The full document has been made available on the MedNet collaborative platform.

detectability of defect/non-compliance. The full document advocates that the factors contribute in differing proportions to the “final risk” of a given case.

5. The full document proposes a model risk classification and prioritization matrix to be customized and used by regulatory authorities. This matrix indicates that regulatory authorities should: (1) identify “risk factors”; (2) establish “importance levels” for each risk factor; (3) define different categories for each risk factor, considering the severity of the case and impacts on the patient’s health and safety; and (4) establish prioritization groups that show the severity and importance of the case for public health. Prioritization will support decision-making in respect of which case to act upon first, what to do and in what timeframe, based on activities pre-defined by each regulatory authority.

6. The full document contains annexed materials to support Member States in the establishment of their own procedures/tools to perform the risk assessment and prioritization of cases. Appendix I presents a catalogue of examples of quality defects in products, for illustrative purposes, and Appendix II presents practical examples of the use of the suggested matrix, for a fictional national context and fictional cases.

ANNEX 2

**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: <ul style="list-style-type: none"> (a) Develop terms of reference; (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; (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; (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)		

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