World Health Organization

SEVENTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS
Agenda item 9

A/MSM/7/6
21 December 2018

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 Alphonce 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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