World Health Organization

SEVENTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS **A/MSM/7/INF./1**
Provisional agenda item 4H **21 November 2018**

Working group to identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet

Terms of reference

Prioritized Activity H – Member State mechanism

INTRODUCTION

1. During the Sixth Meeting of the Member State Mechanism on Substandard and Falsified Medical Products, held in Geneva from 30 November to 1 December 2017, the Member State mechanism (MSM) reviewed a proposal from the Steering Committee (SC) on proposals and priorities for the implementation of the plan of work, corresponding to the 2018–2019 period.

2. Prioritized Activity H aims to establish a Working Group (WG) of the mechanism formed by experts from the Member States to develop the following activities:

(i) develop terms of reference;

(ii) 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 transnationally;

(iii) 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;

(iv) 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.

3. At that meeting, Belgium, China, Indonesia, Ireland, Japan, Spain, Switzerland the United Kingdom of Great Britain and Northern Ireland, and United States of America, expressed their intention to join activity H. In addition, Afghanistan, Brazil and Mexico expressed their support for the creation of the group and to the proposed leadership. Colombia – through National Food and Drug Surveillance Institute, Invima – took the lead in this activity of the MSM 2018–2019 workplan.

GROUP H FORMATION PROCESS

(a) Submittal of an open invitation through the MedNet platform to all Member States to participate in the WG.

(b) The Member States interested in participating sent a Statement of Interest to confirm their participation. Said confirmation included the name and contact information of the experts delegated by each country or of the delegates that would act as points of contact.

(c) Submittal of a direct confirmation message to the 11 Member States that expressed their intention to participate in the group at the sixth MSM meeting in 2017.

(d) The coordinator of the WG sent a request to hold the first virtual meeting to review a draft of the terms of reference and a draft of the biennial operation plan that would be carried out, in order to achieve an agreed version to be submitted for consideration by the MSM through its SC.

(e) The WG set for prioritized activity H functions as a group composed of different countries from different regions. Members of the WG are responsible for establishing the action strategy for the WG, focusing on the identification of experiences and formulation of guidance to address the distribution of substandard and falsified medical products through the internet, as well as cooperation in the organization and monitoring of these activities.

(f) Colombia is the coordinator of the WG, with the support of WHO in the framework of its activities.

(g) Any new WG members will be communicated to the Steering Committee, subject to agreement among the members of the group.

RESOURCES

4. The resources to be used for information exchange between WG members will be decided by the WG, and exchange preferably will be made through virtual sessions and electronic communication. If necessary, any unresolved issues can be discussed and decided in the face-to-face WG meetings in the margins of the MSM annual meeting, in order to finalize the draft documents.

STRATEGIES FOR EACH ACTIVITY

(ii) 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 transnationally

(a) The WG coordinator will send a request for a virtual meeting to present a proposal with the working methodology and tools to be used by the group for the identification of the range of issues that facilitate the sale and supply of substandard and falsified medical products through the internet, both nationally and transnationally.

(b) The WG as a whole will identify the prioritized thematic areas of this activity and, based on that, will propose a workplan with prioritization of objectives, results and deliverables. During the aforementioned process, work and materials that have been developed or are being

developed at the regional and national levels must be considered in order not to duplicate efforts.

(c) The WG coordinator will upload a survey or other data collection tools decided by the WG to the Mednet platform, to be filled out by the Member States.

(d) The WG will define by consensus, as appropriate, experts from countries, who will carry out the consolidation of the results of the tool that allowed the identification of the problem.

(e) For specific technical tasks, any country with previous experience or background in the respective technical topic may designate experts to collaborate in the drafting, adaptation or revision of the diagnostic document with the range of issues that facilitate the sale and supply of substandard and falsified medical products through the internet, both nationally and transnationally. The draft diagnostic document will be evaluated by the WG, which will evaluate whether the documents are ready to be uploaded on to the MedNet and discussed by all Member States. After the period of consultations with Member States, the coordinator of the WG will consolidate the suggestions received in the document, which will be submitted for comments (for clarification purposes) by the WG, whenever necessary.

(f) The coordinator of the WG will send through the Secretariat a final draft document for consideration and relevant decision-making at MSM meetings.

(iii) 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

(a) The WG coordinator will send a request for a virtual meeting to probe for methodologies to 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.

(b) The WG coordinator will upload to the MedNet platform the tool that the Member States will fill out for the identification of 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.

(c) The WG will define by consensus, as appropriate, the experts from countries that will carry out the consolidation of the results of the tool that allow for identification of 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) For specific technical tasks, any country with previous experience or background in the corresponding technical subject can designate experts to collaborate in the drafting, adaptation or revision of the document with 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.

(e) The draft experience and regulation document will be approved by the WG, which will assess whether the document is ready to be uploaded to the MedNet platform and discussed by all Member States. After the period of consultations with the Member States, the coordinator of

the WG will consolidate the suggestions received in a document, which will be submitted for comments (for clarification purposes) by the WG, whenever necessary.

(f) The coordinator of the WG will submit through the Secretariat a final draft document with identification of experiences or regulation of the distribution or supply of medical products via the internet, for final consideration and the relevant decision-making in the MSM meetings.

(iv) 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

(a) The coordinator of the WG will send a request for a virtual meeting to explore suggestions to develop the guidance document on strategies to enable national/regional regulatory authorities to address the distribution or supply of substandard and falsified medical products via the internet.

(b) The WG as a whole will define the structure of the guidance document on strategies to enable national/regional regulatory authorities to address the distribution or supply of substandard and falsified medical products via the internet. During the aforementioned process, previous documents (activities ii and iii) developed by the WG must be considered.

(c) The WG will define, by consensus, which countries will carry out complementary actions that will contribute to the development of the document. For the elaboration of the document of this activity, which will be the final deliverable of the WG, the countries interested in collaborating with the drafting, adaptation or revision of the final guidance document on strategies can designate national experts, or the WG can suggest country experts who can take charge of the elaboration of the final document.

(d) The draft guidance document on strategies will be approved by the WG, which will evaluate whether the document is ready to be uploaded to MedNet and discussed by all the Member States. After the period of consultations with the Member States, the coordinator of the WG will consolidate the suggestions received in a document, which will be submitted for comments (for clarification purposes) by the WG, whenever necessary.

(e) The coordinator of the WG will submit a final draft of the guidance document on strategies to enable national/regional regulatory authorities to address the distribution or supply of substandard and falsified medical products via the internet, for final consideration and relevant decision-making in the MSM meetings.

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