World Health Organization

SECOND MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/ FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS
Provisional agenda item 4

A/MSM/2/2
12 September 2013

Report of the Steering Committee of the Member State mechanism on substandard/spurious/ falsely-labelled/falsified/counterfeit medical products, including the draft workplan as proposed by the Steering Committee

1. The Steering Committee of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products met in Geneva on 26 July 2013 and was chaired by Dr Paul Botwev Orhii (Nigeria) with the following Vice-Chairmen: Professor Papa Amadou Diop (Senegal), Dr Maximilian Derecho on behalf of Dr Carlos Chiale (Argentina), Ms Lou Valdez (United States of America), Dr Reida El Oakley (Libya), Mr Nimo Ahmed (United Kingdom of Great Britain and Northern Ireland), Ambassador Carole Lanteri (Monaco), Mr Hemant Kotalwar (India), Mr Rolliansyah Soemirat (Indonesia), Mr Ding Jianhua (China), and Ms Ruth Lee (Singapore).

2. The Steering Committee based its discussion on the outcome document of the Informal Technical Consultation on the remaining elements of the workplan, which met in Geneva on 25 July 2013.

3. The Steering Committee made suggestions for finalizing the workplan (see the Annex) for the consideration of the Member State mechanism at its meeting on 28–29 November 2013.

4. The Steering Committee identified the advertisement of medical products as an issue requiring further discussion and recommended that this be discussed by the Member State mechanism at its November meeting.

ANNEX

WORKPLAN AS PROPOSED BY THE STEERING COMMITTEE OF THE MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS 26 JULY 2013

1. Strengthening and capacity building of national and regional regulatory authorities and quality control laboratories (both national and regional level) ***(related to Objective 5)***

(a) Identify strengths and weaknesses of national/regional regulatory capacity.

(b) Identify actions to improve Member State/regional regulatory capacities.

(c) Develop and utilize training programmes for capacity building in countries/regions with identified needs.

(d) Promote availability of adequate resources for capacity building.

2. Cooperation and collaboration among national (and regional) authorities and exchange of experiences, lessons learnt, best practices and information on ongoing activities at national, regional and global levels ***(related to Objectives 1, 3)***

(a) Exchange experiences, lessons learnt and information about authentication and detection technologies and methodologies.

(b) Exchange experiences, lessons learnt and information about Track and Trace technologies and methodologies and models.

(c) Exchange experiences, best practices and lessons learnt on cost-effective prevention, detection and control strategies for SSFFC medical products.

3. Communication, education and awareness raising ***(related to all Objectives)***

(a) Vigilance and awareness education among consumers, health professionals and industry.

(b) Advocacy to political leadership.

4. Facilitate consultation, cooperation and collaboration with relevant stakeholders in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective

5. Identify actions, activities and behaviours that result in SSFFC medical products ***(related to Objective 4)***

(a) Identify the activities and behaviours that result in SSFFC medical products being prevented and controlled due to the health risk they present to the population.

(b) Identify those activities and behaviours that fall outside the mandate of the mechanism and separate them from the list of activities and behaviours aforementioned.

6. Strengthen national and regional capacities in order to ensure the integrity of the supply chain *(related to Objectives 1, 2 and 4)*

(a) Identify actions and activities for prevention and control of SSFFC medical products.

(b) Promote the control of distribution channels to prevent SSFFC medical products and strengthen Good Distribution Practices.

(c) Identify actions and activities to address Internet sales that contribute to SSFFC medical products.

(d) Make policy recommendations for Member States and the WHO action/response plan to prevent and control the activities and behaviours identified under 4, suitable to the scope of the Member State mechanism.

(e) Develop terms of reference for national/regional dedicated programme officer or office to address SSFFC medical products.

(f) Develop detection strategies and action mechanisms in case of detection of SSFFC medical products.

(g) Encourage national and/or regional regulatory authorities to have up-to-date directories of legitimate manufacturers and products and to be willing to reveal the status of any manufacturers and products.

(h) Identify a single point of contact from each regulatory authority, for the purposes of SSFFC medical products, and establish a network.

7. Collaboration on surveillance and monitoring *(related to Objective 8)*

(a) Development of methodologies, criteria and tools for data collection and analysis.

(b) Sharing of information on relevant signals, alerts and incidents, including through single points of contact and WHO's Global Surveillance System; this might include consultation, cooperation and collaboration with relevant stakeholders in a transparent and coordinated manner.

(c) Increase regional and global cooperation.

8. Collaboration with and contribution to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products, including but not limited to the supply and use of generic medical products, which should complement measures for the prevention and control of SSFFC medical products *(related to Objective 6)*

(a) Exchange experiences, best practices, and information relating to identifying measures that address access to quality, safe, efficacious, and affordable medical products – including, but

not limited to, the supply and use of generic medical products – and contribute to the existing work of WHO.

(b) Make recommendations to further enhance WHO access programmes to mitigate the risks of SSFFC medical products available to the public.

(c) Increase our knowledge and understanding about the links between the lack of accessibility/affordability and its impact on the emergence of SSFFC medical products and recommend strategies to minimize that impact.

(d) Contribute to raising awareness of policies that hinder access to affordable medical products.

(e) Collaborate and contribute to global efforts through stronger regulatory systems, to work towards making essential/life-saving medical products affordable.

(f) Contribute to the work of other areas of WHO in its efforts at global, regional and country levels for local manufacturing to promote access to quality, safe, efficacious and affordable medical products, recognizing the need for strong regulatory systems.

= = =