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

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Create a focal point network for the exchange of information and consultation at large among Member States and establish an ongoing virtual exchange forum

Terms of reference for the Global Focal Point Network for substandard/spurious/falsely-labelled/falsified/ counterfeit (SSFFC) medical products

Report by the Secretariat[1]

1. The establishment of a global network of focal points for the exchange of information and consultation at large among Member States, and establish an ongoing virtual exchange forum was agreed and prioritized by the Member State mechanism at its third meeting held in October 2014.[2]

2. Recognizing the global nature of the manufacture, distribution and sale of medical products, the Member State mechanism has identified the need for a global network of focal points within WHO Member States to improve the flow and exchange of information from a public health perspective in a safe, secure and efficient environment. The creation of such a network has the potential to improve reporting and alerting of SSFFC medical products, learn from the experience of other Member States and provide access to a reliable source of information in a timely and efficient way.

3. This draft document is intended to provide a basis for discussion in setting the terms of reference for a focal point network relating to SSFFC medical products. It recognizes that networks exist in many regions and subregions and does not attempt to replace any of those networks but rather endeavours to ensure global coordination, consistency and possible integration in approach. The WHO global surveillance and monitoring system for SSFFC medical products has established focal points within national regulatory authorities within over 90 Member States, and these terms of reference would apply to those focal points.

[1] The terms of reference below are based on the original draft prepared by Switzerland, United Kingdom of Great Britain and Northern Ireland and the Secretariat. They take account of comments received from Member States.

[2] See document A/MSM/3/3 Annex 3.

4. Whilst the Member State mechanism has chosen to use the term "focal points" this is interchangeable with the term "single point of contact" currently used in some regions. It is important that the focal point is integrated into existing national and regional alert structures in order to avoid duplication and build synergies. Whilst the National focal point can be a specific group or department within the national medicines regulatory authority, Member States are encouraged to nominate specific personnel within that group or department as focal points, and that those nominated are appropriate for the role, have access to the relevant information and have the support of their senior management to share information in a timely way with the network.

5. The intention of creating this network is to ensure that enquiries and information concerning SSFFC medical products are channelled through to the most appropriate office, and that office is responsible for receiving, communicating and responding to SSFFC-related matters.

6. It is for Member States to identify and nominate the most appropriate office and person(s) to receive, communicate and respond to enquiries relating to SSFFC medical products based on their regulatory and administrative structures.

7. The terms of reference for a nominated national focal point for SSFFC medical products are as follows:

(a) The national focal point should be situated within the national medicine regulatory authority, and acts on behalf of that authority.

(b) To serve as the national focal point representative, Member States are encouraged to nominate a specific member of staff, and where possible a deputy within the national medicines regulatory authority, and their contact details including office address, telephone number and email address provided to the WHO Member State mechanism secretariat. Generic email addresses are acceptable, but the names of the nominated focal points should be notified to the WHO Secretariat. It is the responsibility of national medicine regulatory authorities to inform the WHO Secretariat of any changes in personnel or contact details. The designated focal point is to act only on behalf of its national medicines regulatory authority and not in his/her personal capacity.

(c) With the provision of the contact details to the WHO Secretariat the nominee agrees to the disclosing of his/her contact details to the other National focal points within the network. The WHO Secretariat will regularly circulate and update the list with contact details to all nominated focal points. The list will be treated as strictly confidential by all nominees.

(d) If an existing national focal point or single point of contact within a national medicine regulatory authority for SSFFC medical products has already been identified and/or trained they should be considered for nomination to the network, so as to avoid duplication of effort.[1]

(e) The nominated focal point should be empowered to closely cooperate with the quality control laboratories, national pharmacovigilance centres, national poisons centres and other relevant government entities to ensure that suspected SSFFC medical products are identified and responded to quickly and proportionately.

[1] India is suggesting deletion of subparagraph 7(d) as this is not directly relevant to the terms of reference. The identification and nomination of individuals as focal points should be left completely to national governments.

(f) The nominated focal point should establish effective and efficient working relationships with the appropriate law enforcement agencies and other national institutions and the national criminal justice system to ensure that suspected SSFFC medical products are identified and responded to quickly and proportionately.[1]

(g) The nominated national focal point should be trained on the use of the WHO global surveillance and monitoring system for the reporting of SSFFC medical products, and in compliance with their own Member State laws and regulations concerning disclosure of information pertinent to the WHO surveillance and monitoring system.

(h) The nominated focal point under the direction of the national medicine regulatory authority should be empowered to receive and respond appropriately to all national, regional and global medical product alerts.

(i) The nominated focal point should establish effective and efficient working relationships with health-care providers to ensure that suspected SSFFC medical products are responded to quickly and proportionately.[2]

(j) Where national systems exist for patient reporting of suspected SSFFC medical products, close cooperation between the national focal point and such systems should be established to ensure that suspected SSFFC medical products are responded to quickly and proportionately.[3]

(k) The nominated focal point should establish an effective and efficient working relationship with those engaged in the licensed manufacture, distribution and supply of medical products to ensure that suspected SSFFC medical products are identified and responded to quickly and proportionately.[3]

(l) Nominated focal points should be trained in the use of an electronic platform to be created and administered by WHO Secretariat to enable secure communication with their counterparts from other Member States. All communications under the focal point network should be routed through this online platform.

8. The WHO Secretariat will retain and maintain the list of nominated focal points and administer the secure online platform.

[1] India is suggesting deletion of subparagraph 7(f). Such coordination should be left to the national medicine regulatory authority and not to the designated person. The focal point function should be limited to facilitating communication between WHO and the national medicine regulatory authority regarding issuing an alert or follow-up action after detection of SSFFC medical products. Also, it is impractical to expect this one focal point to have such wide authority.

[2] India is suggesting deletion of subparagraph 7(i). As agreed under the prioritized list of activities for the Member State mechanism, activity B refers to the establishment of a network of focal points for the exchange of information and consultation at large among Member States. Item I of the terms of reference goes beyond this mandate and seems to be prescriptive.

[3] See footnote 1 above.

9. The Secretariat should ensure transparency in its activities with the focal point network and such activities should be reported to the Member State mechanism through the Steering Committee. WHO Secretariat shall ensure that training and other activities with the focal point network shall be free from conflict of interest. In addition, the Secretariat shall not accept any financial contribution from the pharmaceutical or medical devices or diagnostic industry or other non-State actors linked to pharmaceutical or medical devices or diagnostic industry.[1]

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[1] Paragraph 9 inserted by India. However it should be noted that the conduct of the WHO Secretariat is governed by existing rules and procedures.