Appendix 1

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. 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. 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. This document sets out to formalize the terms of reference for the existing focal points within the WHO global surveillance and monitoring system for SSFFC medical products.

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

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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.

that the focal point is situated in existing national and regional medicines regulatory authorities 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 within national medicines regulatory authorities, 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) within the national medicines regulatory authority 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) National medicines regulatory authorities are encouraged to nominate those officials who have the necessary training, expertise or experience for the role as focal point.

   (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.

   (f) 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.
(g) 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.

(h) 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.

(i) 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.

9. The national medicines regulatory authority is encouraged to engage with all relevant stakeholders in preventing, detecting and responding to SSFFC medical products for example, health care providers, law enforcement and the private sector.

10. 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.