World Health Organization

**THIRD MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS**
**Agenda item 8**

**A/MSM/3/3**
**31 October 2014**

# Report of the third meeting of the Member State mechanism on substandard/spurious/falsely-labelled falsified/counterfeit medical products

1. The third meeting of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products met from 29 to 31 October 2014 in Geneva and was chaired by Ambassador Alberto Pedro D'Alotto of Argentina with the following vice-chairpersons: Dr Paul Botwev Orhii of Nigeria; Ms Lou Valdez of the United States of America; Mr Alastair Jeffrey of the United Kingdom of Great Britain and Northern Ireland; Ambassador Carole Lanteri of Monaco; Mr Rolliansyah Soemirat of Indonesia; Dr V.G. Somani of India; and Ms Ruth Lee of Singapore.[1] The session was attended by 63 Member States and one regional economic integration organization.

2. The mechanism reviewed the outcome of the informal technical meeting on recommendations for health authorities to detect and deal with actions, activities and behaviours that result in SSFFC medical products. The mechanism agreed to language proposed by the Chair of the informal meeting for the paragraphs on which agreement had not been reached, with the understanding that the reference to the medical products supply chain in its entirety in paragraph 6 of the outcome document should mean from starting materials to finished products, as indicated in paragraph 8(a). The outcome document is attached at Annex 1.

3. The mechanism reviewed the outcome of the informal technical meeting on element 5(b) of the work plan on the identification of activities and behaviours that fall outside the mandate of the mechanism. The mechanism revised a list of actions, activities and behaviours that fall outside the mandate of the mechanism, but did not reach consensus on the title, a paragraph in the introductory section and elements 3 and 7 of the document. The mechanism requested that the Steering Committee further consult on the document with a view to proposing language for the remaining issues in the paper for submission to the fourth meeting of the Member State mechanism on SSFFC. The outcome document is attached at Annex 2.

4. The mechanism welcomed the Secretariat's presentations on the activities and budget of the Member State mechanism, and expressed concern over the unfunded activities in the budget.

5. Several Member States expressed their intention to contribute to the activities of the Member State mechanism on SSFFC.

[1] The following vice-chairpersons were unable to attend the meeting: Mr Amadou Moctar Dieye of Senegal, Dr Fareha Bugti of Pakistan. WHO has been informed that new vice-chairpersons from the Eastern Mediterranean region and China will be nominated.

6. The mechanism expressed appreciation for the Secretariat's presentation on the WHO Global Surveillance and Monitoring Project. The Secretariat was requested to provide to Member States the schedule of future workshops, further information on the working definitions used by the Secretariat in identifying SSFFC medical products under the project and to further expand the project to cover all regions.

7. The mechanism reviewed a proposal by the Steering Committee on proposals and priorities for implementation of the work plan. The mechanism revised and agreed the list of prioritized activities for 2014–2015, which is attached at Annex 3. With respect to the costs and funding of the activities, the Secretariat was requested to provide updated information for the next meeting of the Steering Committee. Furthermore, the mechanism decided that:

(a) Activity A will be led by Brazil.

(b) Activity B will be supported by Switzerland and United Kingdom of Great Britain and Northern Ireland and that the Secretariat prepare a draft terms of reference for the focal point network for discussion by the Steering Committee at its next meeting and posted on a web platform in advance of the meeting.

(c) Activity C will be led by Argentina.

(d) Activity D will be led by the Secretariat.

(e) Activity F will be led by the Secretariat and would involve the convening of an expert group to conduct the study. Updates on this work, including on the methodology and scope of the study, would be reported to the next meeting of the Steering Committee for consideration and posted on a web platform in advance of the meeting.

(f) Work on the prioritized list of activities should begin in advance of the next meeting of the Steering Committee and begin with electronic consultations using the Secretariat's web platform.

8. The mechanism decided that a study to increase understanding and knowledge on the links between accessibility and affordability and their impact on the emergence of SSFFC medical products and to recommend strategies to minimize their impact will be included on the next provisional list of activities for consideration by the fourth meeting of the Member State mechanism.

9. The mechanism requested the Secretariat to take into account the costing of the mechanism activities in the finalization of the Proposed programme budget 2016–2017.

10. The mechanism requested that at the next meeting the Secretariat provide an update on paragraph 2(11) of resolution WHA67.20 on Regulatory system strengthening for medical products, which request the Director-General to ensure that any activity carried out under the resolution does not duplicate or circumvent the work plan and mandate of the Member State mechanism on SSFFC.

11. The Member State mechanism discussed the review of the Member State mechanism by the Health Assembly in 2016 in accordance with resolution WHA65.19 and decided to request that the World Health Assembly postpone the review of the Member State mechanism by one year.

12. The mechanism decided to request that the Steering Committee discuss at its next meeting the alignment between the commencement and the end/expiration of the term of office of the vice-chairpersons and the term of the rotating chair.

13. The Member State mechanism decided that its next meeting would be held during October or November 2015.

ANNEX 1

# RECOMMENDATIONS FOR HEALTH AUTHORITIES TO DETECT AND DEAL WITH ACTIONS, ACTIVITIES AND BEHAVIOURS THAT RESULT IN SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/ FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS

## I. INTRODUCTION

1. The existence of substandard/spurious/falsely-labelled/falsified/counterfeit (hereinafter SSFFC[1]) medical products in the market and their consequence to public health make national and/or regional regulatory authorities (hereinafter NRRA) face the need for structuring and improving their processes, and establishing proactive strategies for the effective prevention and combat against the actions, activities and behaviours that result in these products.

2. In light of this challenge, it is paramount that the measures implemented by NRRA be previously defined and that authorities be prepared to prevent, detect and take action in cases of actions, activities and behaviours that result in SSFFC medical products. The purpose of this document is not to establish rigid work procedures but to provide guidelines for coordinated action, based on the growing experiences of the countries, which are intended to serve as reference to NRRA for action definition and execution.

3. These guidelines will not exhaust the discussion on the topic, but represent a significant step in the process of strengthening NRRA capacities, with the intent to make them more effective in the interest of protecting public health.

4. The activities described in this guide may be considered and adapted by NRRA, according to the legal, regulatory and operational structure of each country or region, from a public health perspective, excluding trade and intellectual property considerations.

## II. STRATEGIES BY NRRA TO DETECT ACTIONS, ACTIVITIES AND BEHAVIOURS THAT RESULT IN SSFFC MEDICAL PRODUCTS

5. Some tasks and work processes are significant for the detection of actions, activities and behaviours that result in SSFFC medical products:

- quality monitoring (inspections) and control (laboratory testing) in the supply chain;
- alerts from track and trace systems in those countries where such systems have been implemented;

[1] For the purpose of this document, SSFFC will be used in accordance with reference to the footnote in Resolution WHA65.19: "*The Member State mechanism shall use the term 'substandard/spurious/falsely-labelled/falsified/counterfeit medical products' until a definition has been endorsed by the governing bodies of WHO*", and the current document will not prejudge any further negotiation in relation to the definition within the MSM on SSFFC medical products.

- global and/or regional alerts issued from another NRRA and/or WHO;

- reception, assessment and investigation of reports or notifications (generated by any person, such as manufacturers, wholesalers, distributors, consumers and whistle-blowers, as appropriate).

## II.1. Quality monitoring and control

6. Field procedures/inspections are important to verify compliance with national regulations, including current good manufacturing and distribution practices. It is advisable that monitoring activities be carried out in accordance with established procedures, using a risk-based approach that assesses the weaknesses of the medical products supply chain in its entirety and other pieces of information previously obtained, such as the names of the companies involved or tracing activities resulting in the highest number of suspect SSFFC medical products.

7. Therefore, it is important to establish a specific monitoring programme on the distribution chain, including the consideration of compliance history related to good manufacturing/distribution practices, in order to detect SSFFC medical products and evaluate the appropriate documentation held by regulated establishments related to the sale and distribution of the products and the legality of suppliers and customers. Another important point is to take into account the data obtained from quality monitoring and control tasks to determine measures and work processes that strengthen the regulated medical product supply chain and minimize or prevent the introduction of SSFFC products.

8. Based on the established strategies and objectives, the operational approaches should include the following cornerstones:

(a) verification of current good manufacturing and distribution practices in the supply chain of medical products, from starting materials to finished medical product, as appropriate;

(b) verification of the medical products distribution chain, by checking the origin/source and destination for each transaction or transfer of possession;

(c) identification of SSFFC medical products in the chain (through any means, such as post-marketing surveillance, coordination with customs, other law enforcement agencies and marketing authorization holders);

(d) identification and investigation of actions, activities and behaviours that result in SSFFC medical products;

(e) collection of samples for verification and/or analysis;

(f) recall and/or prohibition of the distribution and use of SSFFC medical products detected (including recall at patient's level).

## II.2. Alerts from track and trace systems

9. Product track and trace systems are very useful tools that enable the detection of actions, activities and behaviours that may result in SSFFC medical products.

10. When developing such systems, it is important to observe the circumstances triggering alerts in order to conduct targeted inspections. Some aspects to take account of in alert tracking include the detection of duplicated codes, the attempt to divert serialized products that were previously invalidated for having been stolen, sent out for destruction, intended for marketing outside the national territory, dispensed to patients or any other similar situation.

11. All alerts stemming from track and trace systems must be considered and evaluated; and those posing a greater risk for public health must be prioritized.

### II.3. Reception of alerts, reports and notifications

12. The health NRRA should keep open and accessible communication channels with the public (e.g. health professionals, patients and consumers) and with other relevant authorities providing a method for the public to submit reports or notifications and responding to such submissions in a timely fashion.

13. It is recommended that the reports be received through different ways, such as in-person, by post mail, telephone or e-mail. Reports or notification should be recorded, documented and organized systematically, preferably using a single information system.

14. Regardless of the channels specifically created to receive this type of report, it is advisable that, where appropriate, the report reception system on suspected SSFFC medical products is communicated to pharmacovigilance or investigation systems concerned with product quality problems.

15. Always considering the particular aspects of each case, it is advisable to have the sample, if possible, attached to a report form on the suspected SSFFC medical products containing as much pertinent data as possible, including but not limited to: identification and description of the problem, contact details for the person or entity reporting the problem, product name (International Nonproprietary Name and brand name, if any), batch, manufacturing date, expiry date, manufacturer or marketing authorization holder (hereinafter MAH), location/source where the product was acquired (online, authorized or unauthorized establishment), and description of any adverse events due to the use or application of the suspected SSFFC medical product.

## III. ASSESSMENT OF ALERTS, REPORTS AND NOTIFICATIONS RECEIVED

16. It is recommended that a risk assessment be performed in the evaluation of reports received, bearing in mind the seriousness of the event, the frequency of occurrence and the use of the medical product, to determine the potential impact to public health, as per the relevant national or regional regulatory framework.

17. Some of the elements to be considered when assessing the seriousness of reports include: the therapeutic indication, route of administration, dosage, recommended patient population (e.g. those concerned by the medical fields of paediatrics or geriatrics, pregnant women or others with compromised immune systems), toxicity, potency, narrow therapeutic ratio, chronic use, psychotropic substances and volumes.

18. All notifications should be assessed by the NRRA as soon as possible. Further inspections and eventual corrective actions should be prioritized on the basis of the health risk identified. NRRA and other relevant authorities may utilize covert investigative methods when looking into reports of

suspected SSFFC medical products, collaborating with their law enforcement counterparts, as necessary.

## IV. INVESTIGATION OF ACTIONS, ACTIVITIES OR BEHAVIOURS RESULTING IN SSFFC MEDICAL PRODUCTS

19. In general, the identification or detection of an SSFFC medical product represents a starting point for the identification of the actions, activities or behaviours that caused its occurrence.

20. Investigation is extremely important for NRRA evidence-based decision-making and its purpose is to identify possible threats to public health and their causes. Therefore, this activity requires knowledge, technical skill and the experience of the investigator.

21. Based on the risk assessment and the definition of the cases to be investigated on a priority basis, the approach to suspected SSFFC medical products, and actions, activities and behaviours resulting in SSFFC medical products comprises a series of systematic, specific and supplementary actions and should follow a set yet flexible work procedure, in order for adequate containment measures to be adopted in a timely and effective manner.

22. Every action is to be recorded by the NRRA, preferably, in an investigation file including all gathered evidence, in which all the procedures conducted based on the measures adopted and the information obtained are included chronologically.

23. With a view to taking swift and effective action, it is critical that NRRA establish an action strategy based on the elements and data collected in each case. Some of the aspects and information to take account of include:

- if the action, activity or behaviour was performed intentionally and deliberately;
- if the action, activity or behaviour took place inside or outside of the regulated chain;
- custody of SSFFC medical product sample or the need to obtain the product sample;
- need for conducting an inspection at the product manufacturer or MAH premises among others;
- need for requesting additional information from companies, individuals, organizations or other stakeholders involved in the case;
- need for conducting field surveillance/monitoring actions;
- need for information exchange with other institutions;
- logistical and operational aspects;
- need for establishing a public-oriented dissemination strategy of the case;
- need for information exchange with other NRRA and WHO.

24. The action plan should be dynamic, reviewed and updated based on the results obtained in each case. According to the needs of each case, different activities can be adopted at different times of performance. As an example, actions can be categorized as follows:

**(a) Immediate actions**

- confirming the suspicious SSFFC medical products and characterizing the action, activity or behaviour;
- containing the situation to prevent and reduce the risk to public health from the action, activity or behaviour resulting in SSFFC medical products;

**(b) Short-term actions**

- communicating and disseminating case related information to appropriate parties;
- identifying the persons or entities to be held accountable;

**(c) Long-term actions**

- follow through with the investigation and appropriate health care support.

## IV.1. Immediate actions

25. Actions to be implemented in an urgent manner in order to confirm the suspicion of an SSFFC medical product, and prevent and reduce the risk to public health.

### IV.1.1. Confirming the suspicious SSFFC medical products and characterizing the action, activity or behaviour

26. To confirm the suspected SSFFC medical product, it is useful to have available the allegedly irregular sample in sufficient quantities for laboratory analysis or, at least, some of its components (e.g. packaging and labels), in order to conduct a careful visual comparison with a sample of the genuine authorized product.

27. It is paramount that consideration be given to the differences in elements such as packaging, labels, characteristics and physical aspects of the various components of the product (e.g. shape, colour and odour); general printing characteristics, typography, wording in labels, patient information leaflets/inserts; and batch coding form, manufacture and expiration date.

28. It is advisable that MAHs retain samples of the batches of products and/or packaging materials released to the market, where applicable legislation does not provide for such retention.

29. In case of a report or notification wherein no sample was provided, it is of vital importance to obtain the sample directly from the patient or the establishments where, according to the notification or report, the product is being marketed or used.

30. It is important to include thorough documentation of the handling of such samples and maintain secure procedures for ensuring a transparent chain of custody for possible subsequent criminal

investigation or prosecution where the sample may be used as evidence. In such circumstances, it is critical to maintain the integrity of the sample.

### IV.1.2. Testing in quality-control laboratories

31. The use of basic or complete analytical assays based on methodologies encoded in official standards such as pharmacopoeias, compendia, methodologies of the MAH acknowledged, approved or authorized by the NRRA or others legally accepted, will be useful in reinforcing any determination made on the suspected sample. This will be particularly useful in situations where the physical comparative and/or other sensory-affecting examination between the allegedly SSFFC sample and the authentic medical product has not rendered final conclusions. This testing may represent a measure to determine the composition of the product and assess the product for possible toxicity, contamination, and/or undeclared composition that might cause adverse reactions. This may generate an updated risk assessment.

32. Likewise, even when tests results are satisfactory for a particular sample, it should be taken into account that no knowledge is available about the product's manufacturing process and the quality system adopted by the manufacturer of the suspected sample. On the other hand, it is not possible to ensure dose consistency and manufacture batch homogeneity, which is why the actions, activities and behaviours resulting in SSFFC medical products must always be considered as high risk, regardless of the analytical results.

### IV.1.3. Containing the situation to prevent and reduce the risk to public health from the action, activity or behaviour resulting in SSFFC medical products

#### (a) Prohibition regulations

33. The NRRA should evaluate the need of implementing regulations prohibiting the distribution and use of SSFFC medical products. In this connection, consideration should be given to the possibility of extending the prohibition to the whole product, if the number of SSFFC medical product batches was significant.

#### (b) Recall from market

34. If the batch or batches of products that are linked to actions, activities and behaviours that result in SSFFC medical products detected in the market are related to batches legitimately distributed by the MAH, among others, the NRRA should evaluate the need for ordering to a market recall from distribution channels, in order to minimize the risk to patients.

35. The MAH or the manufacturing authorization holder should audit and qualify the units recovered from distribution channels and inform the NRRA about the results obtained.

36. Disposal and destruction of SSFFC medical products should follow appropriate national or regional legislation or procedures to prevent such products from being reintroduced or sold to the public.

### (c) Contingency plan for supporting patients and their relatives

37. The NRRA, in coordination with concerned stakeholders, should develop plans and procedures for implementing an emergency system when needed, taking into account the following aspects:

- telephone and in-person attention of inquiries;
- collection of samples for verification;
- medical guidance and/or referral to specialized healthcare and/or toxicology centres;
- coordination with relevant stakeholders for additional resources, as needed;
- communication strategy for disseminating the information to the public.

### (d) Reporting the case at international level

38. The NRRA should evaluate the case or cases of detection of actions, activities or behaviours resulting in SSFFC medical products and report to the possible affected Member States. Establishing and maintaining a network of national focal points is crucial for this type of communication.

## IV.1.4. Field actions or inspections

39. Field actions represent an opportunity for the collection of material evidence or evidence of the actions, activities and behaviours that result in SSFFC medical products. Therefore, it is important to establish a monitoring programme for the distribution chain, in order to detect actions, activities and behaviours that resulted in SSFFC medical products and assess the acquisition or possession documentation held by such companies.

40. At national level, there are competent institutions for conducting criminal investigations, should there be criminal provisions stipulated for crimes related to SSFFC medical products. The primary role of the NRRA should be focused on the adoption of health measures and providing support to the institutions conducting criminal investigations.

## IV.2. Short-term actions

41. These actions are concerned with the objective of communicating relevant facts of the case to the public, healthcare professionals and other authorities and relevant stakeholders, as applicable; its potential risks on health; preventing the consumption and exposure by patients; and of identifying the parties involved in the actions, activities and behaviours resulting in SSFFC medical products.

## IV.2.1. Communicating and disseminating relevant information about the case

42. The information about a confirmed case of detection of actions, activities and behaviours resulting in SSFFC medical products should be published on the NRRA official website, with immediate access to its content. It is important that this information be transmitted to the WHO reporting database and to various entities and organizations, in order to complete the measures initiated by the NRRA, with a view to reducing patients' exposure as much as possible.

43. Such information may include:

- general information on the case;
- comparative photographs of the legitimate/authorized medical product versus the SSFFC medical product;
- procedures to be followed by those in possession of medical products with the characteristics of the product identified as SSFFC;
- regions of the country where SSFFC medical products and/or actions, activities and behaviours that result in SSFFC medical products have been detected;
- medical information related to the consumption of the SSFFC medical product.

44. It is important that the actions and activities conducted by NRRAs ensure adequate information be given to the public, while not compromising investigations and judicial activities, if at all possible.

### IV.2.2. Identifying the entities responsible for actions, activities and behaviours that result in SSFFC medical products

45. Where appropriate, the NRRA should share the information with other relevant authorities, the action, behaviour or activity detected that result in SSFFC medical products, and all the evidence in its possession is to be submitted.

46. In this regard, it is important, from a public health perspective, that cooperation between NRRA and other relevant authorities occur in a transparent and coordinated manner.

## IV.3. Long-term actions

### IV.3.1. Maintenance of the alert state

47. The maintenance of the alert state involves a series of activities aimed at detecting new activities, measures or behaviours resulting in SSFFC medical products; evaluating the effectiveness of the measures adopted and the support to patients.

#### (a) Continuity of the monitoring programme

48. The monitoring programme on the distribution chain of medical products should be continued with the purpose of:

- eliminating from the distribution channels those medical products governed by prohibiting regulations issued by the NRRA;
- obtaining any type of information related to the origin of the SSFFC medical products;
- verifying new lines of introduction of SSFFC medical products in the distribution channels;
- verifying the existence of new batches of the identified SSFFC medical product;

- verifying the existence of products with the same active substance and/or the same manufacturer or distributor as those of the SSFFC medical product detected, that may also be SSFFC;

- following up of the market recall after it has been ordered;

- monitoring other batches of the medical product identified as SSFFC by means of tracking and tracing systems.

### (b) Continuity of the contingency plan for health care community support

49. The health care community should be kept apprised of the situation and be instructed to remain vigilant in purchasing practices.

50. Patients and their relatives should continue receiving support for the purpose of following up the cases reported and verifying the possible occurrence of new cases.

## IV.3.2. Continuity of collaboration with authorities in charge of the investigation

51. The NRRA should have at their disposal qualified personnel who can work with authorities in charge of the investigation, in order to provide technical collaboration in investigational procedures that so require it.

# V. ASSESSMENT OF PREVENTION STRATEGIES

52. Results obtained should be assessed, taking into account the behaviours that resulted in the SSFFC medical products and in order to establish strategies to prevent the future occurrence of actions, behaviours and activities similar to those detected.

53. To this end, following a comprehensive assessment of the case, the NRRA may implement, inter alia, new strategies for control; inspectorate strengthening; safety measures on products; legislation oriented to preventing certain actions or behaviours.

## V.1. Strengthening regulatory requirements on medical products

54. Following a comprehensive assessment of the case, the NRRA may implement, inter alia, new strategies for control; inspectorate strengthening; safety measures on products; legislation oriented to preventing certain actions or behaviours.

## V.2. Developing awareness campaigns for the public and healthcare providers

55. NRRAs should develop strategies to raise awareness of actions, activities and behaviours that result in SSFFC medical products. Such awareness campaigns should include the dangers posed by such products, tips on identifying such SSFFC medical products, and recommendations on how to safely purchase medical products.

ANNEX 2

## Actions, activities and behaviours that fall outside the mandate of the Member State mechanism [and separated from the list of actions, activities and behaviours that result in SSFFC medical products] [as they][[and] do not result in a public health risk]

Objective 4 of the MSM's terms of reference as reflected in Element 5 of the work plan mandated the mechanism to identify a list of actions, activities and behaviours that result in SSFFC medical products being prevented and controlled due to the health risk they present to the population and also identify those that fall outside the mandate of the mechanism and separate them from the aforementioned list.

Annex I of document A/MSM/2/6 lists the actions, activities and behaviours that result in SSFFC medical products. The list set out below is a non-exhaustive list of actions, activities and behaviours that fall outside the mandate of the MSM and they should be separated from the actions, activities and behaviours that result in SSFFC medical products. This list could be subject to revisions and adjustments in the future.

[The rationale behind this exercise is to ensure that unauthorized actions, activities and behaviours and medical products will face regulatory actions; whereas authorized actions, activities and behaviours and medical products not posing health risks will not face unjustified regulatory actions, in order not to hamper access to quality, safe and efficacious medical products.]

The term "regulatory authority" used in this paper means the national or regional regulatory authority for medical products.

1. Actions, activities and behaviours in violation of laws other than medical product regulations, such as actions or behaviours in conflict with taxation, duties, customs laws.

2. Actions, activities and behaviours relating to manufacturing, storage, distribution, import and export of quality medical products authorized by the national and/or regional regulatory authority.

3. Actions, activities and behaviours of licensee/authorization holders involving minor deviations, as determined by national and/or regional regulatory authorities, which do not compromise the quality or which do not pose a health risk, [such as minor [unintentional] deviations in good manufacturing practice.]

4. Actions, activities and behaviours related to medical products, exclusively meant for own use of a traveller and carried by himself/herself.

5. Actions, activities and behaviours that are related to the protection or infringement and enforcement of intellectual property rights, including data exclusivity.

6. Actions, activities and behaviours related to medical products meant solely for the purpose of research and development and laboratory testing[,] not for human use.

7. [Actions, activities and behaviours] [in case of medical products in transit, which are in compliance with the regulatory requirements of the country of export and the country of final destination.][which may not be in compliance with the regulatory requirements of the country of transit [while preserving the integrity of the medical product in transit.][and except if there are grounds for suspecting the existence of SSFFC medical products.]]

8. Importing, exporting, distributing, including transporting, storing, supplying or selling authorized/licensed medical products from a country to another country where there is no market authorization/licence existing for that product in order to meet a national emergency, extreme urgency or humanitarian crisis with the consent of the country concerned.

ANNEX 3

## LIST OF PRIORITIZED ACTIVITIES BY THE MEMBER STATE MECHANISMS FOR 2014–2015

| Prioritized activities | Relevant item(s) of the work plan | Activities |
|---|---|---|
| **A. Develop recommendations for the Health Authorities engaged in the detection of SSFFC medical products and establish a strengthening and tool-generating programme to contribute to Member States' training** | 1, 2, 3, 4, 6.(e), 7.(c), 8 | 1. Establish and convene an MSM working group comprised of experts from Member States to:<br>(i) draft recommendations to strengthen NRRAs in their prevention, detection and response to SSFFC medical products, including on criteria for risk classification and assessment prioritization of cases of SSFFC medical products;<br>(ii) develop training material for NRRAs in hard and soft copy, multilingual, virtual and face to face formats focused on the prevention, detection and response to SSFFC medical products. |
| **B. Create a focal point network for the exchange of information and consultation at large among Member States and establish an ongoing virtual exchange forum** | 2, 4, 6.(h), 7, 8.(a) | 1. Develop terms of reference for a focal point network, while utilizing and building upon the existing network of focal points established in 80 Member States and 18 procurement agencies as part of the WHO Surveillance and Monitoring system.<br>2. Develop an online portal to facilitate communication and information exchange.<br>3. Publish a monthly bulletin in addition to WHO Medical Product Alerts. |
| **C. Establish a working group to survey the technologies, methodologies and "track and trace" models in place and to be developed to analyse their advantages and disadvantages and to survey the available authentication and detection technologies and methodologies and analyse their advantages and disadvantages** | 1.(a), 1.(b), 2, 3, 4, 6.(a), 6.(b), 6.(d), 6.(e), 6.(f), 7, 8.(a), 8.(b) | 1. Establish and convene a working group comprised of Member States experts to assess and report on:<br>(a) existing "track and trace" technologies in use by Member States; and<br>(b) existing field detection devices in use or available to Member States. |
| **D. Identify WHO areas working on the issue of access to quality, safe, efficacious and affordable medical products and request a report on the current state of affairs** | 8 | 1. Engage the WHO Secretariat to review and report on all WHO activities on access to quality, safe, efficacious and affordable medical products, from an SSFFC medical products approach. |

| Prioritized activities | Relevant item(s) of the work plan | Activities |
|---|---|---|
| **E. Create a working group to develop and leverage existing recommendations for effective risk communication and recommendations for awareness campaigns on SSFFC medical products and related actions, activities and behaviours.** | 3, 8.(a) | 1. Establish a working group, including communication experts to develop or leverage recommendations for effective risk communication and awareness campaigns specifically tailored for regions/subregions and stakeholder groups.<br>2. Produce samples of hard and soft copy material, video and broadcast material.<br>3. Assess the use of social media for raising awareness.<br>4. Identify full range of stakeholders and audiences.<br>5. Develop key and innovative advocacy material. |
| **F. A proposal for a study on the public health and socio-economic impact of SSFFC medical products** | 3.(b), 8.(c) and 8.(d) | 1. Establish an expert group of health economists to conduct a study on public health and socio-economic impact of SSFFC medical products, convene 3 meetings in Geneva and report. |
| **G. Governance, management and secretariat costs to support the above activities** | | Organizing Member State mechanism meetings, steering committees and working groups. Coordination of activities and implementation by headquarters and regional offices. [1] |

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[1] As endorsed, see document A67/29, Annex 3 on budget and cost implications.