Appendix 1

GUIDANCE ON DEVELOPING A NATIONAL PLAN FOR PREVENTING, DETECTING AND RESPONDING TO ACTIONS, ACTIVITIES AND BEHAVIOURS THAT RESULT IN SUBSTANDARD/SPURIOUS/FAKE-LABELLED/FALSIFIED/COUNTERFEIT (SSFFC) MEDICAL PRODUCTS

INTRODUCTION

1. Actions, activities and behaviours that result in SSFFC medical products are a local and global health problem related to the integrity of the manufacturing and supply chain that must be prevented, detected and effectively responded to, while maintaining a public health perspective.

2. The problem is potentially more severe in countries with weak or nonexistent health regulatory systems and health surveillance infrastructures. These characteristics increase the risk that medical products that are not in compliance with national and regional health regulations will be manufactured and/or distributed – a scenario that puts patients at risk.

3. High prices, inadequate access to affordable medicines, and drugs in shortage are incentives for actions, activities and behaviours that result in SSFFC medical products. These problems must be tackled from the public health perspective.

4. Attention should also be given to the supply of SSFFC medical products through the Internet, given its specificities, the challenges involved in its prevention, detection and effective response, as well as the major dimension this problem has reached globally.

5. Given the nature of the problem and measures related to the prevention, detection and response in respect of actions, activities, and behaviours that result in SSFFC medical products, this guidance must be read from a public health perspective and in accordance with the Member State mechanism’s mandate.

Scope

6. This guidance focuses on the measures and actions to be adopted by national or regional regulatory authorities when developing a national or regional plan, driven by public health concerns, for preventing, detecting and responding to actions, activities and behaviours that result in SSFFC medical products.

7. Collaborative measures and actions with other national, regional and international stakeholders are also described in this guidance.

8. This document presents three goals and the respective desired outcomes to be achieved by a national or regional plan for preventing, detecting and responding to actions, activities and behaviours that result in SSFFC medical products, as well as a road map with examples of actions that might be considered by national and regional regulatory authorities. The road map and the example of actions presented should support the achievement of the three goals, and are by no means exhaustive.
Guiding principles

9. Actions, activities and behaviours that result in SSFFC medical products\(^1\) can involve branded and generic products aimed at the domestic market or the global supply chain.

10. Given the fact that actions, activities and behaviours that result in SSFFC medical products are a public health problem, the definitions adopted by the national or regional plan should be based on a common understanding at international level, where feasible, and take into account public health concerns and practices.

11. Measures adopted by the national or regional plan should take into consideration national policies that support access to medical products, including generic medicines.

12. There is not a one-size-fits-all solution to effectively combat actions, activities and behaviours that result in SSFFC medical products. A multilayer approach that considers prevention, detection, and response strategies is required and should be based on coordination of efforts, exchange of information, and training to strengthen the national or regional health regulatory authority and system.

13. Furthermore, the national or regional plan benefits from a multidisciplinary approach, with the involvement of different stakeholders. Countries or regions with limited resources that are considering developing a plan can benefit from the identification of key action areas in order to ensure that resources can be directed to those activities that will have the most impact first.

14. A national or regional plan would lead to the development of legislative instruments, and legislation enforcement would contribute to the desired outcomes. National or regional legislations on SSFFC medical products should include effective and appropriate enforcement tools and penalties, as well as adequate resources.

---

\(^1\) See Annex 1 of document A/MSM/2/6: actions, activities and behaviours that result in substandard/spurious/falsely-labelled/falsified/counterfeit medical products.
Desired outcomes:

1.1. Reduced actions, activities and behaviours that result in SSFFC medical products
1.2. Improved manufacturing and supply chain integrity
1.3. Improved communication, education, and awareness
1.4. Increased collaboration and cooperation among all stakeholders
1.5. Increased industry responsibility
1.6. Strengthened oversight by regulators.

GOAL 2: BETTER DETECTION OF SSFFC MEDICAL PRODUCTS AND BETTER DETECTION OF ACTIONS, ACTIVITIES AND BEHAVIOURS THAT RESULT IN SSFFC MEDICAL PRODUCTS

Desired outcomes:

2.1. Improved surveillance
2.2. More effective investigation of suspect incidents
2.3. More efficient confirmation that products are SSFFC
2.4. Improved vigilance systems
2.5. More appropriate technology (with consideration given to the technological and financial realities of the national or regional regulatory authority)
2.6. Strengthened capacity and capabilities of laboratories
2.7. Better exchange of information and experiences with all stakeholders.

GOAL 3: MORE EFFECTIVE RESPONSE TO SSFFC MEDICAL PRODUCTS AND MORE EFFECTIVE RESPONSE TO ACTIONS, ACTIVITIES AND BEHAVIOURS THAT RESULT IN SSFFC MEDICAL PRODUCTS

Desired outcomes:

3.1. More effective notification of confirmed actions, activities and behaviours that result in SSFFC medical products
3.2. More effective communication and awareness about detected SSFFC medical products
3.3. More efficient and effective removal of SSFFC products from the market
3.4. Improved response to SSFFC products and actions, activities and behaviours that result in SSFFC medical products
3.5. Improved enforcement
3.6. More effective investigation of confirmed actions, activities and behaviours that result in SSFFC medical products
3.7. Enhanced legal/regulatory tools and measures; and
3.8. Increased collaboration and cooperation among all stakeholders.
ROAD MAP AND EXAMPLES OF ACTIONS

1. Establish or review legislation and regulations aiming at preventing, detecting and responding to actions, activities and behaviours that result in SSFFC medical products

1.1 Develop a compendium of regulatory guidelines related to the issue of actions, activities and behaviours that result in SSFFC medical products

1.2 Assess the existing legislation and identify gaps that allow the entry of SSFFC medical products into the market

1.3 Develop, update and strengthen the legal framework – for example, regulations on marketing authorization, good manufacturing practice, good distribution practice, good pharmacy practice, good pharmacovigilance practice, good importation practice compliance, and good clinical practice – aimed at preventing the actions, activities and behaviours that result in market entry of SSFFC medical products (to be developed and implemented according to good regulatory practices)

1.4 Ensure that only authorized and licensed supply chain stakeholders are involved in medical product transactions.

2. Strengthen capacity of national and regional regulatory authorities

2.1 Increase autonomy and empowerment of national and regional regulatory authorities

2.2 Strengthen capacity on inspections in order to check compliance with the legislation, to identify risks and suspect cases, to implement enforcement actions when non-compliance is detected

2.3 Strengthen capacity for inspections at borders

2.4 Strengthen the capacity for intelligence gathering and investigations on actions, activities and behaviours that result in SSFFC medical products

2.5 Improve good practices of coordination at all levels of governmental authorities, especially in countries where the health surveillance and the health regulatory systems are decentralized

2.6 Include education, increasing awareness and training modules on regulatory affairs in the curricula of regulators (promotion of practices/regulations/guidelines)

2.7 Develop a code of conduct/ethics for regulators

2.8 Engage in regional and global initiatives aimed at developing the strength and capacity of national and regional regulatory authorities

2.9 Create specialized functions, capacities, and capabilities within the national or regional regulatory authority to organize and implement the national or regional plan.

3. Collaborate and/or cooperate appropriately with relevant stakeholders

3.1 Establish sustained, regular and public health-driven partnerships among governmental stakeholders
3.2 Empower the National and Regional Regulatory Authority in the process of coordination and collaboration with other governmental stakeholders

3.3 Establish/maintain channels for communication of the national or regional regulatory authority with all stakeholders, including industry associations, without conflict of interest and from a public health perspective

3.4 Provide databases that can be consulted online by all national (or regional) authorities involved (e.g. authorized manufacturers, wholesalers, registered products, banned or recalled products, etc.)

3.5 Develop and implement investigational/intelligence capacities that go beyond the health regulatory authority (in collaboration with the police, for example)

3.6 Provide multidisciplinary training for the health regulatory staff in the relevant areas of action from a public health perspective

3.7 Adopt strategies for the efficient exchange of information between the governmental bodies involved in the prevention of actions, activities and behaviours that result in market entry of SSFFC medical products, including the provision for a single point of contact system

3.8 When considered necessary by national or regional regulatory authorities, conduct joint national operations and investigations with customs and police, as well as with other relevant stakeholders, from a public health perspective.

4. **Strengthen capacity of other governmental bodies, observing the public health perspective**

4.1 Adjust, if necessary, the existing legal framework adopted by these governmental bodies to public health-driven demands related to the prevention of actions, activities and behaviours that result in market entry of SSFFC medical products

4.2 Include education, increasing awareness and training modules on regulatory affairs in the curricula of the staff in relevant governmental bodies (promotion of practices/regulations/guidelines).

5. **Sensitize stakeholders on the risks of actions, activities and behaviours that result in SSFFC medical products**

5.1 Develop and implement communication strategy

5.2 Develop advocacy documents

5.3 Educate and increase awareness (promotion of practices/regulations/guidelines) specifically to:

   • Health professionals in general
   • Regulated sector
   • Public in general (development of public campaigns).
6. Prevent, monitor and control actions, activities and behaviours that result in the supply of SSFFC medical products through the internet

6.1 Develop a tailored strategy to address the issue of the Internet as a facilitator for the sale and supply of SSFFC medical products

6.2 Develop and implement a communication strategy targeting the supply of SSFFC medical products through the Internet

6.3 Educate and increase awareness to the public in general (development of public campaigns)

6.4 Understand Internet governance and the role of the Internet Corporation for Assigned Names and Numbers. In particular, develop relationships and establish agreements with the domain name registry and registrars, and with hosting service providers and Internet service providers in order to remove and disrupt websites

6.5 Develop relationships and establish agreements with financial merchant service providers in order to remove payment facilities and thereby disrupt the online sale of SSFFC medical products

6.6 Develop relationships and establish agreements with social media providers where SSFFC medical products may be advertised

6.7 Develop relationships and establish agreements with online market places where SSFFC medical products may be sold

6.8 Consider developing a regulatory framework for registering legitimate online sales websites and allocating a logo or other authentication so that consumers can purchase medicines safely.

7. Collaborate to ensure the availability of safe, quality, efficacious and affordable medical products

7.1 Develop and implement national policies for access to generic medical products

7.2 Support authorized local production

7.3 Promote adoption of guidelines to qualify suppliers of medical products and to manage the risks in the supply chain

7.4 Share or exchange experiences, best practices, and information related 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.

8. Strengthen pharmacovigilance system

8.1 Assess the existing national pharmacovigilance system

8.2 Map existing successful national experiences
8.3 Develop/strengthen capacity for pharmacovigilance reporting, including IT systems

8.4 Encourage the reporting of trends to identify patterns in adverse reactions and lack of therapeutic effect

8.5 Establish a complementary system to collect and analyse complaints directly from patients

8.6 Adopt good practices of coordination at all levels of governmental authorities, especially in countries where the health surveillance and the health regulatory system are decentralized

8.7 Improve collaboration and information sharing by national health regulatory authorities on a global scale.

9. **Strengthen post-marketing surveillance programmes**

9.1 Assess the existing national post-marketing surveillance system

9.2 Map existing successful national experiences

9.3 Develop/strengthen capacity for post-marketing surveillance

9.4 Establish a complementary system to collect and analyse complaints directly from patients

9.5 Adopt good practices of coordination at all levels of governmental authorities, especially in countries where the health surveillance and the health regulatory system are decentralized

9.6 Implement a structured and systematic risk-based post-market surveillance programme, in order to ensure efficient use of limited available resources

9.7 Establish or improve risk-based programmes for sampling of medical products for testing by laboratories

9.8 Intensify risk-based inspections of premises and customs controls

9.9 Establish a reliable and cost-effective traceability system for medical products, based on a risk approach

9.10 Implement the use of reliable and cost-effective detection technologies

9.11 Improve collaboration and information sharing by national health regulatory authorities on a global scale.

---

1 See document EB138/40 Appendix 2, Existing technologies and “track and trace” models in use and to be developed by Member States and the document for the current meeting under Activity C.
10. **Strengthen laboratory capacity and capabilities for quality control of medical products and detection of SSFFC medical products**

10.1 Assess the capacity and capabilities of quality control laboratories for the detection and confirmation of suspect cases

10.2 Establish or improve the capacity and infrastructure of quality control laboratories

10.3 Establish inter-country platforms for collaboration and information sharing among quality control laboratories.

11. **Encourage timely and accurate dissemination of information and improve information sharing on incidents nationally, regionally and globally**

11.1 Provide adequate communication of risk

11.2 Develop and conduct training programmes on incident management and risk communication

11.3 Strengthen the coordination at all levels of governmental authorities, especially in countries where the health surveillance and the health regulatory system are decentralized and/or weak

11.4 Take part in international initiatives aimed at sharing information and rapid alerts

11.5 Train focal points, establish and implement procedures to report SSFFC medical products to monitoring and alert systems, including the WHO global surveillance and monitoring system

11.6 Develop infrastructure, activities, capacity-building and operational mechanisms for sharing of information

11.7 Regularly update and publish a compendium of authorized pharmaceutical establishments and medical products.

12. **Ensure the timely intervention of national and regional regulatory authorities to react quickly and proportionately, in order to safeguard public health, to incidents involving actions, activities and behaviours that result in SSFFC medical products**

12.1 Implement procedures for suspension of marketing authorization, quarantine, recall/return of suspect medical products, safety alerts and destruction of SSFFC medical products

12.2 Adopt procedures for regulatory authority rapid response\(^1\) when a suspect SSFFC medical product is identified

---

\(^1\) See document A/MSM/3/3 (Annex 1).
12.3 Adopt procedures for regulatory authority rapid response when an action, activity or behaviour that results in SSFFC medical products is identified.

12.4 Adopt good practices of coordination at all levels of governmental authorities, especially in countries where the health surveillance and the health regulatory systems are decentralized.

13. **Ensure adequate enforcement and collaboration from the public health perspective**

13.1 Sensitize and implement joint training initiatives involving the following: customs, police, legislature, judiciary and prosecutors.

13.2 Actively investigate, prosecute and sanction in accordance with national legislation the actions, activities and behaviours that result in SSFFC medical products.

13.3 Monitor measures and results of the actions taken by the police, customs, and regulatory authorities for preventing, detecting and responding to actions, activities and behaviours that result in SSFFC medical products.