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## **Report by the Secretariat**

1. The first meeting of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products discussed the scope of the Member State mechanism, areas of work and workplan, structure and governance, funding, and dates of the next meeting.
2. The meeting decided, as a first activity of the new Member State mechanism, to establish an Open-ended Working Group to identify the actions, activities and behaviours that result in SSFFC medical products, in line with resolution WHA65.19, Annex, objective (4).
3. As a contribution to the first meeting of the Member State mechanism, Brazil provided a “non-paper” on actions, activities and behaviours that result in SSFFC medical products and that need to be identified. The non-paper, entitled “*Practices of health authorities and WHO in the process of ensuring the quality, safety and effectiveness of medical products*” is annexed to this report.
4. The non-paper was also posted on the web-based platform (<http://mednet.who.int/ssffcbehavior>) on 13 June 2013 to invite feedback and comments from Member States in preparation for the discussion by the Open-ended Working Group on behaviours that result in substandard/spurious/falsely-labelled/falsified/counterfeit medical products.
5. Argentina, Mali and the United States of America posted comments on the non-paper on the web-based platform within the deadline of 10 July 2013. These comments are available at <http://mednet.who.int/ssffcbehavior> and hard copies will be available in the meeting room, together with any additional feedback received.

ANNEX

**PRACTICES OF HEALTH AUTHORITIES AND WHO IN THE PROCESS  
OF ENSURING THE QUALITY, SAFETY AND EFFECTIVENESS  
OF MEDICAL PRODUCTS**

*Brazil's contributions to the "4th objective" and the scope of the Member State mechanism  
(resolution WHA65.19)<sup>1</sup>*

**(A) Premises to characterize the necessary measures to guarantee the safety, effectiveness and quality of medicines offered to the population**

- (1) The main objective of health regulation and health control is to protect the population against health risks. Health authorities have a duty to establish rules and instruments that control the production, distribution and commercialization of medical products so as to ensure the quality, safety and efficacy of those products.
- (2) There are several irregular forms of production and commercialization of medical products that circumvent the rules and health requirements.
- (3) Therefore, health authorities must ensure that only medicines meeting the requirements of quality, safety and efficacy are produced. Health authorities should also find measures to ensure that medicines which do not comply with health requirements do not reach the population.
- (4) For the purposes of health surveillance, it is more efficient, productive and relevant to identify activities and behaviours that should be prevented and controlled (those that entail health risks) instead of finding definitions for irregular products resulting from these activities and behaviours, since such products may be identified using distinct terminologies determined by domestic legislation and linguistic particularities (e.g. false products/counterfeit/falsified/fake).
- (5) The description of the activities and behaviours that negatively impact the quality, safety and efficacy of medicines may assist health authorities in identifying the agent and the irregular product. More than a concept, the identification and characterization of these activities and behaviours enables the assessment of the risk to the population, as well as measures that can be adopted to prevent and control these activities and behaviours and these irregular products.
- (6) Although activities and behaviours may be described through the use of distinct terminologies that identify them in each country, **the definition of** an activity and behaviour **must entail a descriptive exercise**, so that their content is represented by the actions (*to produce, to commercialize, to distribute, to store*) and by the agents who practise them.

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<sup>1</sup>See resolution WHA65.19, Annex, Objectives: "... (4) To identify actions, activities and behaviours that result in "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" and make recommendations, including for improving the quality, safety and efficacy of medical products."

With the above-mentioned considerations in mind, the following elements are necessary for such a descriptive exercise:

- Agent: subject of action; one that performs the action. This may be the registration holder or any other company or individual regularized, or not, by the relevant health authority.
- Description of activities and behaviours: This is the characterization of the action or inaction that causes harm or the danger of harm. There must be a verb discriminating the action: to make, to alter, to modify, to produce, to commercialize, to import, etc...

### **(B) What should be defined?**

- **The question to be answered is:**

“What activities and behaviours should domestic health authorities (with the support of WHO) **prevent and control?**”

- **and not:**

“What **products** should domestic health authorities (with the support of WHO) **prevent and control?**”

### **(C) What are the activities and behaviours that health authorities should prevent and control?**

Necessary condition: Such activities and behaviours put the health of the population at risk.

The identification of the elements of the activities and behaviours to be prevented and controlled could contribute to the definition of the scope of the Member State mechanism to deal with SSFFC.

### **Examples of activities and behaviours that put at risk and/or damage public health, classified according to the elements aforementioned:**

#### *In the stage of product manufacturing:*

#### **(1) Activities and behaviours of the holder of the health registration of the medical product:**

(IMPORTANT: This refers to the health registration of medicines and not trademark registration)

- Produces medicines that violate the registered formula, either in relation to the active ingredient (e.g. medicines without active ingredient, or with incorrect concentrations of active ingredients) or in relation to excipients (e.g. risk of ineffectiveness or toxicity);
- Fails to comply with good manufacturing practices (GMP);
- Modifies the packaging, without complying with health regulations and without authorization from the health authority;
- Repacks the product in order to circumvent inspection activities or modifies the expiry date of the product;

- Modifies the manufacturing process of medical products, without the authorization of the health authority, jeopardizing the therapeutic activity of the medicine;
- Fails to implement good manufacturing practices whether by recklessness, negligence or malpractice (e.g. an accidental mix of components/inputs/active principles or packaging material).

**(2) Activities and behaviours of a third party (practised by agents who do not hold title to the health registration of medicine):**

(IMPORTANT: This refers to the health registration of medicines and not to the trademark registration)

- Manufactures medical products in establishments that are not authorized by the health authority;
- Manufactures medical products without registration or approval by the health authority;
- Steals batches of medical products and changes their packaging with the purpose of hindering the tracking and tracing of batches or extending the expiration date of the products;
- Reproduces registered medicines or their packaging without authorization of the health authority;
- Substitutes the contents of the medical product using an authorized packaging.

(NOTE: for all the aforementioned cases, the actions of the health authorities should focus on all the agents involved in the process of falsifying the medicines – whether or not the activities and behaviours are secondary.)

***In the stage of product distribution***

***(import, export, distribution, transportation, storage and commercialization of medical products):***

- Imports, exports, distributes, transports, stores and commercializes medical products without authorization from the health authority;
- Fails to comply with the best practices of distribution, transportation and storage of medical products, as set out in the national health regulations;
- Imports, exports, distributes, transports, stores and commercializes medical products without health registration;
- Imports, exports, distributes, transports, stores and commercializes medical products that have been purchased from unauthorized companies or are of unknown origin;
- Changes the dates of manufacture and of expiry on the medical product's packaging;
- Fails to implement good practice in the distribution, transportation or storage of medical products, whether by recklessness, malpractice or negligence.

**(D) What activities and behaviours are irrelevant for the purposes of this discussion?**

Finally, it is necessary to list the activities and behaviours that are irrelevant for purposes of the current discussion.

An example is the conflict regarding ownership of patents, i.e., it does not matter to this discussion whether a producer is a patent holder or not. What matters is whether or not a producer holds a valid **health registration** and **authorization to operate** granted by the health authority.

Moreover, trademark infringement is a violation of a private right and does not relate to health regulation and the protection of public health.

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