World Health Organization

FOURTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS
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Extract from document A68/33, Annex 2

This document reproduces the text of Annex 2 of document A68/33 for the purpose of the deliberations of the fourth meeting of the Member State mechanism on substandard/spurious/falsely-labelled falsified/counterfeit 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.

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