

Report of the informal technical working group on draft working definitions of substandard/spurious /falsely-labelled/falsified/counterfeit (SSFFC) medical products

1. The informal technical working group on working definitions met on Tuesday 22 November 2016 and was chaired by Mr Maximiliano Derecho (Argentina).
2. Representatives from 10 Member States were present.
3. The outcome of the discussions and recommendations agreed by the informal technical working group are attached to this report in the Annex.

ANNEX

WHO MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT (SSFFC) MEDICAL PRODUCTS

Recommendations from the informal technical working group on draft working definitions

INTRODUCTION

1. At the fourth meeting of the Member State mechanism on SSFFC medical products held on 19 and 20 November 2015, the decision was taken¹ to establish a working group on refining the working definitions of SSFFC medical products,² based on those currently used by the WHO global surveillance and monitoring system. This decision followed comments received from Member States with reference to the working definitions document circulated on the MedNet platform in 2015, which have been consolidated in the present paper.

Scope

2. This working group seeks to achieve a simplified common global understanding and provide clarity of what is meant by the term “SSFFC medical product” to Member States and all other stakeholders; and to recommend a definition of what constitutes a SSFFC medical product to the fifth meeting of the Member State mechanism.

3. In this sense, in the terms of reference set out in resolution WHA65.19 (2012)³ it was stated in the relevant footnote that “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. Previous discussions between Member States show that there would be a consensus among them to accept the use of the term “falsified” for the purposes of the work carried out within the Member State mechanism. Should consensus among Member States be achieved, the term “SSFFC” could, therefore, be replaced by that agreed by them.

4. It is not intended to propose, or affect in any way, national and/or regional legislation either in existence or that may be drafted in the future by Member States and/or regional organizations relating to SSFFC medical products. No matter which terms are adopted by each Member State, it is important to have a clear understanding about the terms and their correlation with the working definitions adopted by the Member State mechanism.

Methodology

5. The classification of reports of SSFFC medical products to WHO permits a more thorough and accurate comparison and analysis of reports, separating substandard medical products from those that

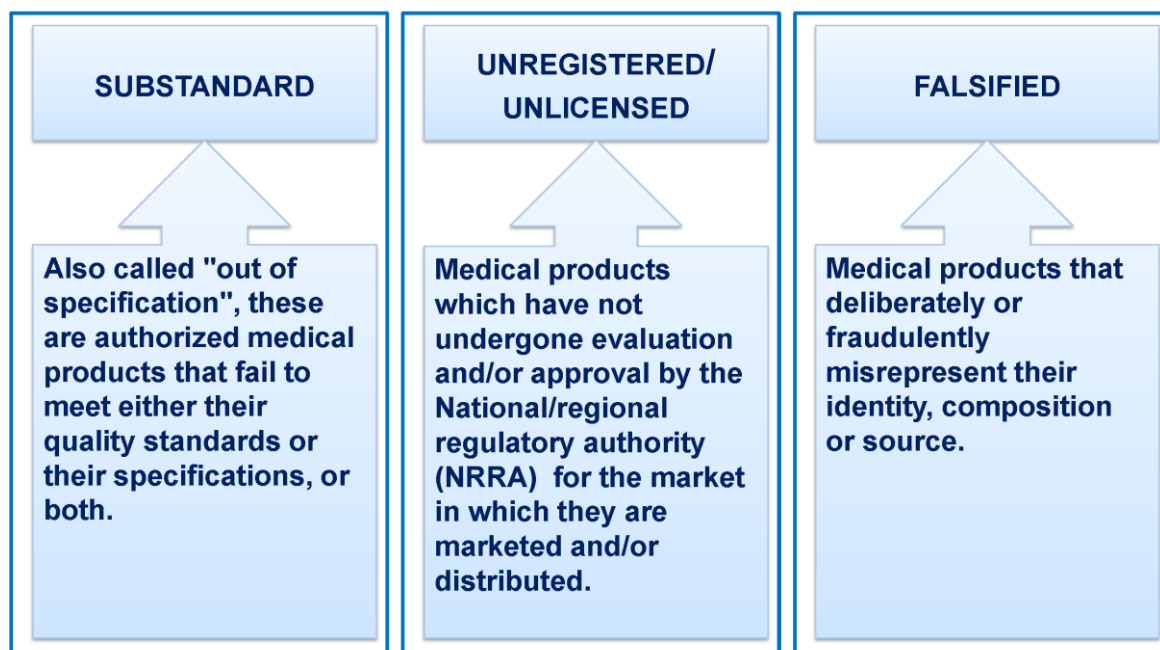
¹ See document A/MSM/4/10.

² A medical product is defined as a medicine, vaccine or in vitro diagnostic (paragraph 3 document A/SSFFC/WG/5) and it may also include medical devices at an appropriate time in the future.

³ See document WHA65/2012/REC/1.

are deliberately/fraudulently making a misrepresentation (spurious, falsely-labelled, falsified or counterfeit) and those that are unregistered/unlicensed in the country of marketing (see Figure).

Figure. Classification of medical products to be used by the WHO global surveillance and monitoring system and the Member State mechanism



6. The classification table shown in the Figure above sets out three separate and mutually exclusive classifications of medical products reported to the WHO global surveillance and monitoring system.

7. For the purpose of this document and the classifications below, **Authorized medical products** means medical products in compliance with national and regional regulations and legislation. NRRAs can, according to national or regional regulations and legislation, permit the marketing or distribution of medical products with or without registration/license.

(a) Substandard medical products

*Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or their specifications, or both*¹

(b) Unregistered/unlicensed medical products

Medical products that have not undergone evaluation and/or approval by the NRRRA for the market in which they are marketed and/or distributed.

¹ When the authorized manufacturer deliberately fails to meet these quality standards or specifications due to misrepresentation of identity, composition, or source, then the medical product should be considered "falsified".

These medical products may or may not have obtained the relevant authorization from the national/regional regulatory authority of its geographical origin.

(c) Falsified medical products

Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

Any consideration related to intellectual property rights does not fall within this definition.

Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product.

“Identity” shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized medical product.

“Composition” shall refer to any ingredient or component of the medical product in accordance with applicable specifications authorized/recognized by NRRA.

“Source” shall refer to the identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor or retailer, as applicable.

Medical products should not be considered as falsified solely on the grounds that they are unauthorized for marketing in any given country.

Intellectual property rights

8. The terms of reference of the Member State mechanism on SSFFC medical products expressly exclude the protection of intellectual property rights from the mandate of the mechanism and, therefore, the same criteria shall be used in the definitions to be used in its deliberations and work. The term “counterfeit” is now usually defined and associated with the protection of intellectual property rights. For reference purposes, the definitions of “trademark counterfeit goods”¹ and pirated copyright goods² are included as defined under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

9. In the context of medical products, the term “falsified” appears to adequately include all the various types of deliberate misrepresentation of a medical product in such a way which enables the specific exclusion of intellectual property rights.

¹“Trademark counterfeit goods: goods, including packaging, bearing without authorization a trademark that is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation”.

²“Pirated copyright goods: any goods that are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production, and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.”

Conclusion and recommendation

10. This document is not intended to be an exhaustive examination of legal texts and definitions, but; rather, it is meant to start the process of simplifying the current terminology in use by the WHO global surveillance and monitoring system and the Member State mechanism from a public health perspective.

11. Based on the deliberation of the working group it is recommended that the Member State mechanism replace the use of “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” with “substandard and falsified medical products”, as the term to be used in its name and in all future documentation on the subject of medical products of this type.

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