
Report of the Open-ended Working Group to Identify the Actions, Activities and Behaviours that Result in Substandard/Spurious/Falsely- labelled/Falsified/Counterfeit Medical Products

1. The Open-ended Working Group to Identify the Actions, Activities and Behaviours that Result in Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit Medical Products met from 23 to 24 July 2013 in Geneva and was chaired by Bruno Neves Silva (Brazil). The session was attended by 73 Member States and one regional economic integration organization.
2. The Working Group based its discussion on a “non-paper” provided by Brazil, entitled “Practices of health authorities and WHO in the process of ensuring the quality, safety and effectiveness of medical products”, which was annexed to the report by the Secretariat contained in document A/MSM/WG/1/2.
3. The Working Group’s discussions were characterized by a spirit of goodwill and flexibility and it reached agreement on a number of actions, activities and behaviours that result in substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products. The Working Group recognized that issues for further discussion include: advertising that misleads the public or purchasing entities; corruption and conflict of interest; and lack of effective labelling of medical products.
4. It was also recognized that discussions are needed on section D of the annex to the Secretariat’s report,¹ entitled “What activities and behaviours are irrelevant for the purposes of this discussion?”.
5. The outcome of the Open-ended Working Group’s deliberations is attached (see the Annex) for the consideration of the Member State mechanism at its meeting.

¹ Document A/MSM/WG/1/2.

ANNEX

THE OUTCOME OF THE DELIBERATIONS OF THE OPEN-ENDED WORKING GROUP TO IDENTIFY THE ACTIONS, ACTIVITIES AND BEHAVIOURS THAT RESULT IN SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS

1. The Open-ended Working Group to Identify the Actions, Activities and Behaviours that Result in Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit Medical Products, in order to protect public health and promote access to affordable, safe, efficacious, and quality medical products, has identified the following actions, activities, and behaviours that result in substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products. This is a non-exhaustive list that could be subject to revisions and adjustments in the future. The guiding principle is to prevent and reduce the risk to public health from SSFFC medical products, ensuring that only medical products meeting the national and/or regional regulatory authority requirements are manufactured, imported, distributed and supplied:

- manufacturing medical products in establishments that are not authorized by the national and/or regional regulatory authority;
- manufacturing medical products or their packaging or their labelling without registration or approval by the national and/or regional regulatory authority;
- modifying accompanying information of the medical products and changing their packaging and extending the use-before date or expiration date of the products which misleads the public and/or purchasing entities;
- substituting the contents of the medical product using the authorized packaging;
- importing, exporting, distributing, including transporting, supplying, selling, including through the Internet, as appropriate, and storing medical products without compliance to applicable national and/or regional regulations and requirements;
- manufacturing, importing, distributing, supplying or selling medical products:
 - (a) without registration or approval or authorization by the national regulatory authority; or
 - (b) using an authorization that does not exist; or
 - (c) using without permission an authorization already granted to another¹ by a national and/or regional regulatory authority;

¹ The term “another” refers to products or manufacturers, importers, distributors, suppliers, or sellers of medical products.

- manufacturing medical products which replicate registered medical products or their packaging without authorization of the national and/or regional regulatory authority;
- failing to comply with good practices of manufacturing, distribution, transportation and storage of medical products, as set out by the national and/or regional regulatory authority;
- importing, exporting, distributing, including transporting, storing, supplying or selling medical products obtained from an unauthorized or unknown origin;
- manufacturing medical products that violate the formula or the data contained in the registration file as approved or accepted by the national and/or regional regulatory authority;
- modifying the packaging and/or the labelling, without complying with national and/or regional regulations and without authorization from the national and/or regional regulatory authority.

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