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 that 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 another\(^1\) by a national and/or regional regulatory authority;
- 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;

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