Substandard and falsified medical products (SFMPs) – Glossary of terms

Term (acronym)	Definition
Adverse event	Any untoward medical occurrence in a clinical trial subject administered a pharmaceutical product; it does not necessarily have a causal relationship with the treatment.
Batch number	A defined quantity of starting material, packaging material or product, processed in a single process or series of processes, so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.
Benchmarking	A measurement or point of reference at the beginning of an activity which is used for comparison with subsequent measurements of the same variable.
Competency	Competency combines knowledge, skills and attitudes. Competencies describe how the work is to be carried out, while objectives indicate what must be accomplished. They also provide a sound basis for consistent and objective performance standards by creating a shared language for what is needed and expected by the organization.
Expiry date	The expiry date placed on the container of a product designates the date up to which (including) the product is expected to remain within specification, if stored correctly. It is established for every batch by adding the shelf-life period to the manufacturing date.
Global benchmarking tool (GBT)	A WHO developed tool and the primary means by which WHO assesses regulatory systems for the regulation of medical products. The tool and benchmarking methodology enable WHO and regulatory authorities to: identify areas of strength as well as areas for improvement; facilitate the formulation of an institutional development plan to build upon strengths and address identified gaps; aid in the prioritization of investments in the institutional development plan; and help monitor progress. The WHO GBT is the first truly global tool for benchmarking regulatory systems, unified from previous WHO tools.
Global Surveillance and Monitoring System (GSMS)	A comprehensive initiative by WHO aimed at preventing, detecting and responding to substandard and falsified medical products. GSMS plays a crucial role in enhancing the global response to substandard and falsified medical products by providing a robust framework for data collection, analysis, reporting and capacity-building. GSMS also provides key services to WHO Member States, including: data collection and analysis; reporting and communication; risk assessment and surveillance; capacity-building and training; technical assistance and support; and global collaboration and coordination.
Governance	Refers to the different ways that organizations, institutions, businesses and governments manage their affairs. Governance is the act of governing and thus involves the application of laws and regulations, but also of customs, ethical standards and norms. Good governance means that affairs are managed well, not that the laws, regulations or norms are themselves necessarily good.
Manufacturer	A company that carries out operations such as production, packaging, repackaging, labelling and relabelling of pharmaceuticals.

SFMP: substandard and falsified medical product; WHO: World Health Organization.

World Health Organization

Term (acronym)	Definition
Market surveillance	The activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in legislation and do not endanger health, safety or any other aspect of public interest protection (based on European Union Council Directive EC No 756/2008 of 9 July 2008 concerning the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93).
Medical product	Products including, but not limited to, finished pharmaceutical products, medical devices, vaccines and in vitro diagnostic products.
Member State Mechanism	This mechanism was established at the 2012 World Health Assembly to address substandard and falsified medical products in a transparent and inclusive way from a public health perspective and expressly excluding considerations of intellectual property rights. A World Health Assembly resolution was passed against a backdrop of increasing concern about such products and the health and socioeconomic harms they cause. WHO serves as the Secretariat of the Member State Mechanism. The mechanism aims to protect public health and promote access to affordable, safe, efficacious and quality medical products, and to promote through effective collaboration among Member States and the Secretariat, the prevention and control of substandard and falsified medical products and associated activities
Monograph	In the context of WHO, monographs provide detailed information on specific medicinal substances or products, including their properties, uses, dosage forms, quality standards and safety information. Monographs serve as authoritative references for health care professionals, manufacturers, researchers and regulatory authorities to ensure the quality, safety and efficacy of medicines.
National medicines regulatory agency (NMRA)	The NMRA is responsible for the registration of and other regulatory activities concerning medical products, such as medicines, vaccines, blood products and medical devices.
National regulatory system (NRS)	The NRS provides the framework that supports WHO. The system is composed of entities responsible for the registration, marketing authorization and other regulatory functions concerning medical products. The number of regulatory entities responsible for different regulatory functions may vary from one country to another.
Packaging	Packaging relates to all operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product. Sterile filling would not normally be regarded as part of packaging, the bulk product being the filled, but not the finally packaged, primary container.
Pharmaceutical product	Any product intended for human use, or a veterinary product intended for administration to food-producing animals, presented in its finished dosage form, which is subject to control by pharmaceutical legislation in either the exporting or the importing state. This includes: products for which a prescription is required; products that may be sold to patients without a prescription; biologicals; and vaccines. It does not include medical devices.
Pharmacopoeia	A pharmacopoeia is an official publication containing a list of medicinal products with their effects and directions for use. The main objective of a pharmacopeia is to protect public health by creating and making available public standards to help ensure the quality of medicines. Pharmacopoeia standards support regulatory authorities in controlling the quality of pharmaceutical substances, their finished pharmaceutical products and related materials. It provides a tool with which the user or procurer can make an independent judgement regarding quality, thus safeguarding the health of the public.

Term (acronym)	Definition
Process	A set of interrelated or interacting activities that use inputs to deliver an intended result. In the context of NRAs [national regulatory authorities], the production and service provision processes should coincide with basic regulatory functions.
Quality control	Quality control relates to all measures to ensure that specifications, sampling, testing and analytical clearance of raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.
Rapid alert	An urgent notification submitted by an NRA [national regulatory authority] participating in the rapid alert system on measures taken against a product placed on the market that poses a risk to consumer health and/or safety.
Recall	A process for withdrawing or removing a pharmaceutical product from the distribution chain because of defects in the material or complaints of a serious nature. The recall might be initiated by the manufacturer/importer/distributor or a responsible agency.
Regulation	A written instrument containing rules having the force of law.
Regulatory authority	A government body or other entity that exercises a legal right to control the use or sale of medical products within its jurisdiction, and that may take enforcement action to ensure that the products marketed within its jurisdiction comply with legal requirements.
Regulatory framework	The collection of laws, regulations, guidelines and other regulatory instruments through which a government controls the manufacture, clinical evaluation, marketing, promotion and post-marketing safety benchmarking of medical products.
Stakeholder	Any individual, group or organization that can affect, be affected by, or perceives itself to be affected by a risk. Primary stakeholders are the patient, health care professional, medicines regulatory authorities and the pharmaceutical industry.
Substandard and falsified (medical products)	A substandard medical product is an authorized product that fails to meet either its quality standards or its specifications, or both. A falsified medical product is one that deliberately and fraudulently misrepresents its identity, composition or source.

WHO: World Health Organization.