Substandard and falsified medical products

Regulatory self-assessment tool

2023

Colophon

International Pharmaceutical Federation (FIP)
Andries Bickerweg 5
2517 JP The Hague
The Netherlands
www.fip.org

Editors
Brett Simmonds, Chair, FIP Professional Regulators Advisory Group 2022–2023, and Pharmacy Board of Australia
Ronald Guse, Past-Chair, FIP Professional Regulators Advisory Group 2020–2022, Canada
Al Carter, National Association of Boards of Pharmacy, USA
Carmen Catizone, National Association of Boards of Pharmacy, USA
Adele Fifield, National Association of Pharmacy Regulatory Authorities, Canada
Hélène Leblanc, French Chamber of Pharmacists, France
Luís Lourenço, International Pharmaceutical Federation, Portugal
Marie-Hélène Morzadec, French Chamber of Pharmacists, France
Anastasia Shiamptanis, National Association of Pharmacy Regulatory Authorities, Canada
Andi Shirtcliffe, Ministry of Health, New Zealand
Leonor Soares, Portuguese Pharmaceutical Society, Portugal
Carine Wolf-Thal, French Chamber of Pharmacists, France
Zuzana Kusynová, FIP Lead for Policy, Practice and Compliance
Aysu Selçuk, FIP Policy, Practice and Compliance Manager

Recommended citation
International Pharmaceutical Federation (FIP). Substandard and falsified medical products: Regulatory self-assessment tool. The Hague: International Pharmaceutical Federation; 2023.

Cover image
©Thanakorn Lappattaranan | iStockphotos.com

Contents

1 Introduction

1.1 Background

In 2017, the World Health Organization estimated that more than one in 10 medicines in low- and middle-income countries was either substandard or falsified (SF). The direct result of this is that these countries spend well over USD 30 billion annually on SF pharmaceutical products — a figure that excludes the full range of socio-economic costs to individuals and societies.

SF pharmaceutical products are often difficult to detect, even for trained professionals. While failing to treat patients (often with serious consequences), they may not cause obvious adverse reactions but, even when detected, they are often under-reported, which would otherwise prevent wider harm.

FIP is seriously concerned about the ever-increasing risk to public health of SF pharmaceutical products, particularly in countries where legislation governing the manufacture and distribution of medical products, or the enforcement of legislation, is either non-existent or ineffective. The circulation of poor quality, harmful and counterfeit active ingredients and finished products in international commerce seriously reduces the quality of patient care and increases the risk of harm to people. Falsification and poor quality completely undermine the long-established controls of quality, safety and efficacy of medical products that are designed to protect the public. The key to the reduction in the impact of SF medical products is detection, quarantine and destruction.

Ministries of health, governmental regulatory agencies, pharmacists and pharmacy teams must play a major role in detection and preventing SF medical products reaching patients and the wider public. FIP has been speaking out against SF medical products for over 20 years and the self-assessment tool that we present here is another mechanism to decrease the impact of SF medical products on patient care.

As the health care professionals at the last interface with patients in the pharmaceutical supply chain, pharmacists are key to combating and minimising SF pharmaceutical products. In community and hospital settings, pharmacists can quickly detect SF pharmaceutical products that have penetrated supply chains and report them to authorities, as well as educate and advise patients who have been exposed to or are considering using them.

1.2 Aim of the tool

This regulatory self-assessment tool seeks to aid the detection of, quarantine and removal of SF medical products from the pharmaceutical supply chain in a country and to prevent SF medical products from being used by patients. It also includes SF medical products incident information sharing and public awareness.

Clearly, this tool is not setting up pharmacists or pharmacy staff as the sole healthcare providers to combat SF medical products. The self-assessment tool identifies the role of ministries of health, and FIP intends that this regulatory framework be adopted for other healthcare professions and become applicable to all healthcare workers.

In addition to ministries of health, other relevant competent authorities and institutions must act to protect the public and educate healthcare professionals and all participants in the supply chain on the risks of SF medical products, their detection and methods to protect the integrity of the supply chain.

1.3 Using the tool

Recognising that SF medical products are an unacceptable and preventable public health threat, this tool is developed for countries to self-assess the status of their current legislation to prevent, detect and remove SF medical products in their medical product supply chain.

Patient safety and quality are required at all levels to guarantee supply chain integrity and product quality and require full involvement of government and government officials regulating the distribution of medical products as well as healthcare professionals, namely pharmacists, who work closest with the medical products and who are the last interface for patients receiving medical products for their personal use.

This regulatory self-assessment tool was developed for countries to use to review their current legislation comprehensively, examining not only what the tool contains but also its intended applications and the breadth of issues it addresses. Where weaknesses or legislative gaps are discovered, the sections contained in this document could be adopted or adapted and become part of legislative framework to combat SF medical products coming into the medical product supply chain. The tool can also be used as an educational resource to raise the awareness of the risk and harm of SF medical products among all healthcare providers and healthcare policy makers, as well as being included in undergraduate and professional programmes.

Typically, new or changing legislation can be slow and difficult to draft and enact, but regulations can be made through a simpler and more agile process. Implementation of a prevention, detection and removal legislative framework for SF medical products might require additional clarifying policies or standards which become the real “how to” guide for regulators and healthcare professionals.

FIP, its Regulators Advisory Group and its member organisations can be used as a resource for the drafting and development of supportive regulations, policies, standards of care and training programmes. Using this tool to its fullest can create a legislative framework for a medical product supply chain that is void of SF medical products.

2 Substandard and falsified medical products: Regulatory self-assessment tool for pharmacy intervention

The tables below list and describe the factors of practice, and roles of pharmacy and ministries of health that may require specific regulations. This list can be used to assess gaps in regulations or the language of existing regulations. For each practice element or role, a rationale and a proposed language for regulations are provided. The proposed language can facilitate the development or update of regulations, but should be adapted as appropriate to each local context. The last column can be used to identify gaps in the legislation and regulations currently in place and the need to adopt or adapt the suggested wording.

With any impactful legislation and regulations, definitions must be included to clarify the meaning of the words being used and to ensure proper compliance. In this document, it Is strongly recommended the definitions be included and embedded in the legislative framework.

2.1 Definitions

Objective	Description and proposed language for legislative/regulatory requirements	Are these regulations in place in your jurisdiction?
Substandard and falsified medical products (can also contain spurious or counterfeit medical products): "SF medical product"	Substandard medical products as those which fail to meet their quality standards or specifications. Falsified medical products are medical products that deliberately or fraudulently misrepresent their identity, composition or source. Falsified products include products not licensed for use in a particular country, illegal reproduction, substandard, adulterated and any product produced from unsafe or unlicensed manufacturing. SF medical products are defined as either substandard, falsified or both.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
Medicine/ medical product	"Medicine" means a prescription or non-prescription drug, herbal or traditional product, compounded preparation, active pharmaceutical ingredient or an excipient (non -active) ingredient. It is a substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient

Objective	Description and proposed language for legislative/regulatory requirements	Are these regulations in place in your jurisdiction?
	"Medical product" is broader than medicine and means products primarily utilised by healthcare professionals for the diagnosis, treatment or prevention of disease or injuries. "Medical product", therefore, includes medicine.	
Quarantine	Quarantine is the physically separate storage or clear demarcation of a medical product to prevent its use, distribution or transfer. A quarantined medical product is a non-saleable product.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
Pharmacy	A pharmacy is a facility licensed for any aspect of the practice of pharmacy.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
Medical product wholesaler/ distributor	"Medical product wholesaler" or "distributor" means a corporation, individual or other entity that buys medical products for resale and distribution to corporations, individuals or entities other than consumers.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient

Objective	Description and proposed language for legislative/regulatory requirements	Are these regulations in place in your jurisdiction?
Ministry of health*	A ministry of health, from a legal and regulatory perspective, serves as the governing body responsible for overseeing healthcare practices and policies within a country or jurisdiction. It sets and enforces standards, licenses health care professionals, regulates pharmacy facilities, and ensures compliance with health laws to safeguard public health and maintain quality care delivery. (*In some jurisdictions it may be another competent authority that holds this responsibility. However, in this document, the term “ministry of health” is used.)	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
Sale/ sell	To sell means to advertise for sale, offer for sale, offer to arrange for another person to sell, expose for sale, have in possession for sale, supply, or distribute, whether or not the distribution is made for payment or other beneficial consideration.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
Disposal	Disposal of medical products means the discarding of medical products, eventually leading to their destruction in an appropriate manner, and removal from the supply chain.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
Non-saleable product	A non-saleable medical product is one that cannot be sold or distributed further. This prohibition does not include distribution as quarantined medical products for analysis or destruction.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient

Objective	Description and proposed language for legislative/regulatory requirements	Are these regulations in place in your jurisdiction?
Trusted supplier	A trusted supplier is a manufacturer, wholesaler or other pharmaceutical distributor that is licensed and regulated ensuring medical products are manufactured or distributed in a manner that is compliant with all laws of the jurisdiction and country.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient

2.2 Role of pharmacy

Objective	Description and proposed language for legislative/regulatory requirements	Are these regulations in place in your jurisdiction?
Receiving and storage	A pharmacist who meets the required qualifications may, subject to any restrictions or conditions set out in the regulations and in the course of the practice of pharmacy, engage in the act of prescribing/administering vaccines that are designated in the regulations, ensuring the safety and efficacy of these vaccines, especially in the context of combatting substandard and falsified medicines.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
SF medical products training	A pharmacy must provide knowledge and training to all pharmacy staff involved with the pharmaceutical supply chain and with ordering, receiving, unpacking and dispensing of medical products on the risks of SF medical products. The training should explain the reasons for SF medical products (both direct and indirect). The training should cover all the important aspects related to awareness of SF medical products, and the actions the staff can take. For example, on the detection of falsified medical products it should cover the action to be taken upon suspecting a falsified product and the harm of falsified medical products can cause to unsuspecting patients. The training should include close examination techniques of the medical product source, labelling and packaging, and the medicine dosages to detect SF medical products. It should also cover the actions to take once an SF medical product is detected, its reporting, related communication and patient counselling.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
Duty to detect	Pharmacy team members involved with the drug supply chain have a duty to be vigilant in their assessment of all medical products being sold to the public or distributed in other means.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient

Objective	Description and proposed language for legislative/regulatory requirements	Are these regulations in place in your jurisdiction?
Duty to quarantine	A pharmacist or pharmacy team member who has reason to believe a medical product in inventory at the pharmacy is substandard or falsified must immediately quarantine those medical products and report the details of the concern to the pharmacist manager or pharmacy owner. The medical product cannot be reintroduced into the active inventory until such time as a review of the concerns or qualified assessment confirms the medical product is safe and legal for use.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
Duty to report	Upon confirmation medical product is falsified, the pharmacist, pharmacy manager or pharmacy owner must report the incident to at least one of the following: 1) Ministry of health; 2) The department within the ministry of health responsible for ensuring the quality and safety of medical products; and 3) Federal, provincial or municipal law enforcement, regulatory body and, as appropriate, international regulator.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
Duty to ensure patient safety	A pharmacist and any person on the pharmacy staff must apply a visual assessment on medical products being used in the dispensing process for the possibility of their being falsified.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
Duty to inform patients	If a medical product is suspected or determined to be substandard or falsified and quarantined causing a substantive delay in the dispensing process, the patient must be informed of the reason for any delay. Should the patient already be in possession of the falsified medical product, the patient and the prescriber must be informed immediately, and the patient referred for a medical assessment.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient

Objective	Description and proposed language for legislative/regulatory requirements	Are these regulations in place in your jurisdiction?
Duty to follow SF medical product alerts	The pharmacy must ensure that all pharmacists and pharmacy dispensary staff are provided with falsified medical product alerts received from the ministry of health or other approved resources.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient

2.3 Role of ministries of health

Objective	Description and proposed language for legislative/regulatory requirements	Are these regulations in place in your jurisdiction?
Report and investigation	A ministry of health must conduct or ensure the following tasks are done, as appropriate, in response to a SF medical product report: 1) Carry out examinations and laboratory analysis in a timely manner to verify the medical product is safe to use or is substandard and/or falsified; 2) Perform supply chain compliance verification activities to confirm source of SF medical product and deploy compliance or enforcement measures appropriate to the incident; 3) Notify healthcare regulatory bodies and publish public advisories and warnings on SF medical product, as appropriate; 4) Identify the parties responsible for the entry and distribution of SF medical products into the supply system and take criminal action against the offending parties; and 5) Notify federal or regional law enforcement and regulatory bodies and international regulators.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
Public awareness and healthcare education	Ministries of health, authorities and relevant institutions must educate the public, health professionals and participants in the supply chain of the risks of SF medical products, their detection and methods to protect the integrity of the supply chain.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient

Objective	Description and proposed language for legislative/regulatory requirements	Are these regulations in place in your jurisdiction?
Law enforcement	The sale of SF medical products is a violation of the criminal code. Depending on the nature of the violation, a ministry of health has the legislated authority for the following actions: 1) The issuance of advisory and warning letters; 2) Immediate court actions, such as seizure or injunction; 3) Administrative actions, such as administrative detention to gain control of SF medical products, mandatory recall of SF medical products, or suspension of a facility's licence or registration; and 4) Court actions involving fines and imprisonment.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
Prevention	Prevention mechanisms in place enable regulatory authorities to take measures against SF medical products and their manufacturers. Investing heavily in tools and technologies to prevent, deter and detect SF medical products, and to create procedures that can assist health-care professionals and patients to identify genuine products are helpful strategies. An online accreditation programme and a ministry of health website should be developed or adopted directing the public to safe online vendors and websites. International regulatory and professional collaboration are required to ensure that prevention mechanisms can be successfully implemented and expanded where they are lacking.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
Supply chain integrity	Throughout the pharmaceutical supply chain, from manufacturer to patient, distribution points and storage data are recorded and verified, and the data move with the medical product.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient

Objective	Description and proposed language for legislative/regulatory requirements	Are these regulations in place in your jurisdiction?
Coordination of stakeholders	Ministries of health inform and coordinate national and regional governments, global organisations, the private and non-profit sectors, and civil society to prevent incidents of SF medical products.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient
Strong pharmacovigilance reporting systems	Ministries of health develop SF medical products reporting systems that are readily accessible to all healthcare professionals, providing timely confirmation and immediately sharable results and information on a local, regional, national and international basis.	☐ Yes ☐ No ☐ Yes, but need updating ☐ No, but the regulatory environment is sufficient

2.4 Additional notes

Additional notes *For objectives identified as a priority, use this section to indicate priority sequencing and implementation requirements*

2.5 References

1. The World Health Organization (WHO). Global Surveillance and Monitoring System for substandard and falsified medicines, vaccines and in-vitro diagnostic tests. 2017, Geneva. Available from: https://apps.who.int/iris/bitstream/handle/10665/326708/9789241513425-eng.pdf
2. Combating falsified medical product-related crime: a guide to good legislative practices. 2019, Vienna. Available from: https://www.unodc.org/documents/treaties/publications/19-00741_Guide_Falsified_Medical_Products_ebook.pdf
3. Curriculum for pharmacy students on substandard and falsified medicines: Curriculum guide and competency framework. 2021, The Hague. Available from: https://www.fip.org/file/4917

International
Pharmaceutical
Federation

Fédération
Internationale
Pharmaceutique

Andries Bickerweg 5
2517 JP The Hague
The Netherlands
-
T +31 (0)70 302 19 70
F +31 (0)70 302 19 99
fip@fip.org
-
www.fip.org