Prioritization and risk parameters related to substandard and falsified medical products

This section leaflet must be used in conjunction with the leaflet entitled: *Questions to consider when assessing risk.* (section 5.1.6 of the SFMP trainer's toolkit).

The parameters given are only suggestions that may be used to:

- assess the level of different risk types, and
- prioritize resources to deploy appropriate mitigation and control measures.

The information given in this leaflet can be adapted to different contexts of conducting risk assessment of an incident of a substandard and falsified medical product (SFMP), taking into account factors such as response capacity, socioeconomic environment and reliance opportunities.

Note. This document does not cover medical devices, including in vitro diagnostics.

Risk assessment and management of SFMP incidents

The goal of risk assessment is to identify and prioritize actions that will mitigate the threat. Risk assessment is a systematic process of gathering, assessing and documenting information to assign a level of risk Table. It provides the basis for taking action to manage and reduce the negative consequences of SFMPs.

The risk management cycle includes the identification and prioritization of mitigation measures, taking into account the likelihood of success, the feasibility of implementation and unintended consequences. Resources are never unlimited and this applies to any organization. Resource management determines the quality of the SFMP incident response.

Multistakeholder engagement is always encouraged to establish all necessary facts. There may not be full confidence in the information available initially. In this case, further information should be sought, and the risk assessment repeated as appropriate. Risk assessment is a continuous (but not always sequential) process, and each new piece of information will help refine the assessment. Risk management also requires continuous monitoring and evaluation as the incident unfolds.

Handling SFMP incidents in a professional, consistent, timely and proportionate manner requires sound risk assessment and will reflect well on the organization(s) involved.

[1] Threat is the potential harm that can occur. Risk is the likelihood that the harm will be realized.

Prioritization and risk parameters by type

Type of risk	Risk level	Criteria
Critical		
Public health	High	Fatalities or serious adverse reactions, or Immediate or likely threat of fatalities or serious adverse reactions, or Multiple numbers of persons affected (> 500, or depending on population size)
	Medium	Severe adverse reactions, or Threat of severe adverse reactions, or Multiple numbers of persons affected (> 100, or depending on population size)
	Low	Threat of severe adverse reactions, and Low numbers of persons affected (< 100 or depending on population size), or Isolated incident
Supply chain	High	Product already in the regulated/licensed supply chain, and Reached hospitals, clinics, pharmacies or patients, or Recall likely to lead to a considerable shortage
	Medium	Product available only through unlicensed and unregulated outlets
	Low	Product not thought to be available to the public
Geographic	High	Product available on an inter-regional or global basis, including unregulated websites
	Medium	Product restricted to one region
	Low	Product restricted to a small area
Environmental	High	Serious or immediate risk to the environment
	Medium	Potential risks to the environment
	Low	No environmental risks identified
Associated		
Public interest	High	Widespread and escalating international media interest, or Patient group or other major stakeholder interest, or Risk of serious reputational damage to public authorities or organizations
	Medium	Regional or national media interest, or Subject of complaints to/from stakeholders
	Low	No significant public interest
Political	High	Subject of significant national government interest
	Medium	Affecting or likely to affect, change or undermine policy
	Low	Non-contentious issue
Economic	High	Major financial gain or serious loss > US$ 1 million (or depending on socioeconomic environment)
	Medium	Financial gain or loss < US$ 1 million (or depending on socioeconomic environment)
	Low	No significant gain or loss
Legal	High	Organization(s) exposed to litigation or other legal challenges
	Medium	Weakness exposed in the regulatory or legislative systems
	Low	No perceived legal risks
Historical		
Product history	High	Same batch/lot of product previously notified
	Medium	Same product previously notified
	Low	No previous reports
Supply-chain elements	High	Same importer, exporter, broker, wholesaler, distributor or retailer
	Medium	Similar method or pattern of transportation, concealment of products or payment
	Low	No previous reports