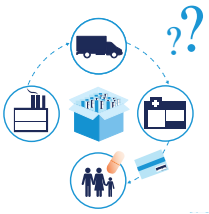
Substandard and falsified medical products (SFMPs) – questions to consider when assessing risk

This document is supplementary material to the SFMP trainer's toolkit and must be used in conjunction with the document, *Prioritization and Risk Parameters* (section 5.1.5 of SFMP trainer's toolkit).

Critical risks

Public health risks

- Have there been any reports of health events associated with the reported/suspected SFMP, for example, suspected adverse reaction? What is the severity?
- How many people/patients have been affected or may be affected in the future?
- What is the profile of the population exposed to the risk (e.g. children, vulnerable populations and difficult-to-reach people)?
- Were all the adverse reactions reported from the same location/point of care/health care professional?
- Is it likely that the adverse reaction was caused by method of administration or use (e.g. injection device, self-administration or self-medication) instead of the therapeutic itself?



Supply-chain risks

- Is the reported/suspected SFMP in the regulated or illicit/unregulated supply chain? Was it properly registered and imported?
- At what point in the supply chain was the incident discovered (e.g. by the patient, pharmacy, hospital, wholesaler or manufacturer)?
- How many different batch numbers (and unique combinations of variable data) are involved?
- What volumes of product have been reported? How many doses/treatment regimens?
- Who supplied the reported/suspected SFMP, and who else may have received it (e.g. public/government procurement agency, NGOs or aid organizations and private sector)?
- What other products have been procured through the same supply route?
- How many production sites of the reported/suspected SFMP exist? What is their production capacity?
- Could the issue affect other products produced in the same sites?

Geographic risks

- Where was the incident discovered (e.g. border area, major transport hub or in transit)? Where else is the reported/suspected SFMP likely to be available?
- Is the reported/suspected SFMP available in a wide range of locations? In what quantities?
- Could the reported/suspected SFMP have been smuggled/stolen/in transit (i.e. a consignment such as a container temporarily in one port or location before reaching its final destination)?
- Are there packaging elements that suggest the reported/suspected SFMP may be widely available geographically (e.g. packaging in multiple languages or multiple registration numbers)?

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

World Health Organization

Environmental risks

- Are there factors associated with the environment, health status, behaviours, social or cultural practices, health infrastructure and legal and policy frameworks that increase a population's vulnerability to the reported/suspected SFMP?
- Would the services of a specialized laboratory be required? Is there any risk of environmental contamination if the reported/suspected SFMP is disposed of inappropriately?

Associated risks

Public interest

- Would a recall cause panic/distrust/other significant reaction from the public (alert versus alarm)?
- Are the media likely to report on the incident? Is the subject material likely to generate media interest (e.g. involves children, high profile organizations, a relatable story or multiple sources)?
- Has the incident been reported by multiple independent sources (e.g. residents, news media and health care workers)?
- How likely is the situation to get out of control or cause significant alarm in terms of public communication? Is there an effective system for communication between incident managers and other stakeholders?
- Who supplied the reported/suspected SFMP (e.g. public/government procurement agency, NGO or aid organization)?

Political

- Who reported/discovered the product in the first place? Could there be ulterior motives?
- Who has been involved in and informed of the incident at this stage? For example, are local authorities taking action; if so, what are the local political implications to be taken in account?
- Is the reported/suspected SFMP manufactured/distributed/procured by organizations or individuals who may have conflicts of interest?

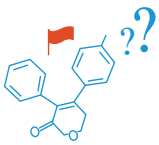
Economic

- What is the volume/size of the seizure/discovery of the reported/suspected SFMP?
- Is the reported/suspected SFMP comparatively expensive? Will replacement by a good-quality and safe version have a substantial economic impact (and on whom)?
- Is the population who uses the product exposed to risk of financial hardship when procuring the product (economic vulnerability)?
- Would the response/mitigation/control measures have a substantial cost (e.g. recall, laboratory analyses and replacement therapies)?
- Are there many pharmaceutical production/distribution sites that are affected?

Legal

- Is there a legal framework that empowers/enables the implementation of mitigation/response/control measures, especially if immediate/urgent action is required?
- Is your organization at risk of litigation in relation to the reported/suspected SFMP? Could any such legal process hinder the implementation of mitigation measures?
- Does your organization have any legal obligations related to the quality and safety of the reported/suspected SFMP? Were there any quality management processes that could have been overlooked?
- Who is legally responsible for the manufacture/distribution/quality/authorization of the reported/suspected SFMP?

Historical risks



Previous history of product

- Is it likely that the same adverse reaction may have occurred before elsewhere and not be noted?
- Is there a previous similar record (e.g. finished product, active ingredient or therapeutic indication) in your own database, the WHO GSMS database, the database of another similar organization, or in the media/open-source intelligence?

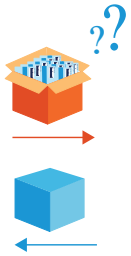
Previous history of supply-chain element or stakeholder

- Has a similar incident been reported previously (e.g. with a similar presentation, affecting a similar population and geographical area, over the same time period)?
- Is there a previous similar record (e.g. manufacturer's name or importer's name) in your own database, the WHO GSMS database, the database of another organization, or in the media/open-source intelligence?
- Does the incident present a recurring pattern in the supply-chain distribution and/or operational method?
- Have there been any associated or previous events (e.g. product recalls or similar events in neighbouring countries)?

General questions to assess response capacity and impact

Mitigation/control measures to prioritize

- Can the treatment be continued with an alternative product?
- What type of product is affected? For example, is the product on an essential medicines list, is it a life-saving product? Is this product marketed/distributed/available abroad, either formally or informally? Can help be obtained from colleagues in other organizations to support resource planning and risk mitigation (e.g. analysing information, distributing alternative treatments)?
- Could there be any form of contamination in different batches/lots (e.g. pathogenic microorganisms or another active ingredient)? Is the issue at the level of finished product or active pharmaceutical ingredients?
- Is specialized and/or lengthy and/or costly laboratory testing required? Can WHO assist?



Consequences of response measures

- Can the same number of doses be easily replaced and/or alternative treatment be provided? What would be the impact of a recall?
- What is the availability and acceptability of effective preventive measures and treatment?
- Are there any access issues related to the reported/suspected SFMP (e.g. existing or projected shortage or likelihood of medication being shared between patients)?
- What is the market turnover and the shelf life of the reported/suspected SFMP?

Source: WHO, 2017.