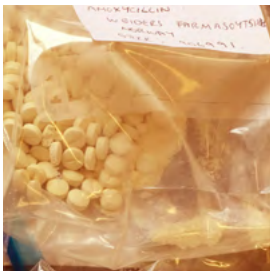
Identifying suspected substandard and falsified medical producs (SFMPs) for healthcare professionals

This document outlines warning signs suggesting a medical product may be substandard or falsified. It is predominantly for use by healthcare professionals but can be adapted for use by other public health actors.

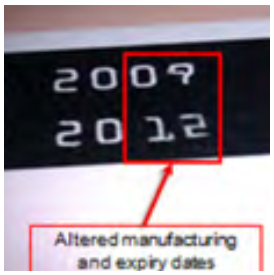
Substandard and falsified medical products are often difficult to detect. The following signs should raise suspicion. Please note that this guide is not an exhaustive list.

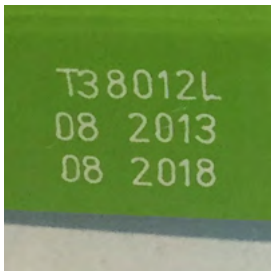
Therapeutic effect	• Patients report that the product is not working properly (unexpected lack of efficacy), and/or • Patients suffer unexpected adverse reaction(s)
Outer packaging	• Packaging is not in good condition, and/or • Manufacturers details are not clearly stated, and/or • Incorrect language, with grammatical and spelling errors, and/or • Batch numbers and expiry/manufacturing dates appear altered
Inner packaging	• Batch numbers, manufacturing/expiry dates on inner packaging (e.g. blister pack) are different from outer packaging, and/or • Patient information leaflet is in the wrong language
Supply source	• Any suspicion is raise on the source or price of a product and authenticity of accompanying documents, and/or • Any suspicion is raised on quantities available, e.g. products that are usually in short supply are suddenly available regularly or in large quantities
Other factors	• Product does not look, smell, taste and feel correct (i.e. texture), and/or • Packaging components are empty or separated, and/or • Product was not properly stored

Substandard example



Falsified example





If in doubt, please contact your national health authorities, who should then liaise with the WHO Global Surveillance and Monitoring System on SFMP.

Follow guidance provided in the aide memoire on how to manage an SFMP incident.

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

World Health Organization

Notes for health care professionals

Therapeutic effect

- Is there an unexpected lack of efficacy? Often the product will not cause a toxic reaction but will fail to treat the condition for which it was intended, with potentially devastating consequences. For example, a patient failing to respond to their anti-infective will rarely consider that the cause of the problem may be their medicine.
- Is there an unexpected adverse reaction? Some SFMPs do cause adverse reactions and sometimes fatalities. A patient may experience an unexpected or unusual worsening of their medical condition.

Outer packaging and inner packaging

- Is the packaging in good condition? The container should protect the medical product inside (e.g. properly sealed and airtight).
- Are the manufacturer's details (e.g. name, logo, hologram, full address and registration number) clearly stated and in the correct language for the market/country in which the product is distributed?
- Are there any spelling or grammatical errors?
- Are the batch/lot numbers and manufacturing and expiry dates altered? They should be clearly shown, not possible to erase and easily readable, and there should be no irregularity in the embossing or imprinting.
- Is the dosage form or product strength clearly indicated on the label and the same on all parts of the packaging?
- Is the information the same on the inner and outer packaging, with no signs of alteration and discrepancies?
- Is there a patient information leaflet and is it in the correct language? The information on the patient information leaflet should match the information on other parts of the packaging. There should be no irregularity in printing quality or colour, shape, texture and size of paper (e.g. smudged ink, overly thick or rough paper).

Supply source

- Are there any suspicions about the source, price and quantities available (e.g. sudden availability of a product that is usually in short supply), or authenticity of accompanying documents? Those engaged in the manufacture, distribution and supply of SFMPs understand the market and respond quickly to demand. SFMPs can penetrate the legal supply chain through hospitals, clinics, pharmacies and wholesalers who have obtained medical products from unknown sources and intermediaries without checking their credentials or conducting any due diligence.

Other factors

- Did the patient (or did you) notice that the medical product looked, tasted, smelt or felt different? Any irregularity in the uniformity of appearance (i.e. colour, shape, texture, size and clarity), flavour and smell should raise suspicion.
- Are there any empty or separated packaging components (e.g. bottle caps, spoons, bottles, flat packs and capsules)? Such incidents may indicate signs of smuggling or tampering.
- Was the product properly stored? Storage conditions (e.g. temperature and humidity) should be stated on the label and maintained. Signs of degradation may include leakage and discolouration.