World Health Organization

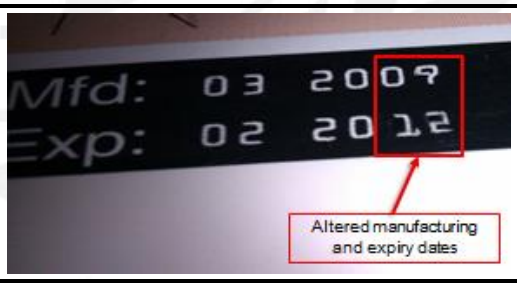
IDENTIFYING SUSPECT SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS

Some substandard and falsified medical products are almost visually identical to the genuine product and very difficult to detect. The following signs should raise your suspicion

Please note that this guide is a non-exhaustive list

THERAPEUTIC EFFECT	▪ Patients report that it is not working properly (unexpected lack of efficacy), or ▪ Patients suffer unexpected adverse reaction(s)
OUTER (SECONDARY) PACKAGING	▪ Packaging is not in good condition, or ▪ Manufacturers details are not clearly stated, or ▪ Incorrect language, grammatical and spelling errors, or ▪ Batch numbers and expiry dates appear altered
INNER (PRIMARY) PACKAGING	▪ Batch numbers, manufacturing and expiry dates on inner packaging (e.g. blister) are different to outer packaging, or ▪ Patient information leaflet is in the wrong language
SUPPLY SOURCE	▪ Any suspicion on the source, price, or authenticity of accompanying documents, or ▪ Any suspicion on quantities available, for example products that are usually in short supply are suddenly available very regularly or in large quantities
OTHER FACTORS	▪ Product does not look, smell, taste and feel correct, or ▪ Packaging components are empty or separated ▪ Product was not properly stored

SUBSTANDARD EXAMPLE



FALSIFIED EXAMPLE

IF IN DOUBT, VERIFY THE TO THE GLOBAL SURVEILLANCE AND MONITORING SYSTEM PORTAL AND REPORT PRODUCT OR CONTACT RAPIDALERT@WHO.INT

FOLLOW GUIDANCE PROVIDED IN THE AIDE-MEMOIRE ON HOW TO MANAGE AN INCIDENT OF AN SF MEDICAL PRODUCT

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GUIDE FOR HEALTHCARE 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-malarial will rarely consider that the cause of the problem may be their medicine.
- **Is there an unexpected adverse reaction?** Some substandard and falsified medical products do cause adverse reactions and sometimes fatalities. A patient may experience an unexpected or unusual worsening of their medical condition.

OUTER (SECONDARY) PACKAGING AND INNER (PRIMARY) PACKAGING:

- **Is the packaging in good condition?** The container should appropriately protect the medical product inside (e.g. properly sealed, airtight, etc.).
- **Are the manufacturer's details clearly stated and in correct language?** The manufacturer's details (name, logo, hologram, full address, registration number, etc.) should be correct and in the appropriate language for the market/country in which the product is distributed.
- **Are there any spelling or grammatical errors?** There should be no spelling or grammatical errors, particularly for the trade (brand) name and active ingredient(s).
- **Are the batch/lot numbers and manufacturing and expiry dates altered?** They should be clearly indicated, should not be possible to erase, be easily readable, and there should be no irregularity in the embossing, impressing or imprinting.
- **Is the dosage form or medicine strength clearly indicated on the label?** They should be the appropriate strength and dosage form for the medicine and be the same on all parts of the packaging.
- **Is the information the same on the inner and outer packaging?** This information should be the same on all parts of the 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 be clearly indicated and should match the information on other parts of the packaging and product container. There should be no irregularity in how it is printed and the quality of the colour, shape, texture, and size of paper (e.g. ink should not be smudged, paper is not too rough, etc.).

SOURCE OF SUPPLY:

- **Is there any suspicion on the source, price, quantities available, regularity of products that are usually in short supply or authenticity of accompanying documents?** Those engaged in the manufacture, distribution and supply of substandard and falsified medical products have shown they respond quickly to demand, thoroughly understanding the market and are fast to exploit opportunities. Most commonly, substandard and falsified medical products enter the legal supply chain at distribution level 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. For example, products whose price appears unusually low, or which are available in unusually large quantities should raise suspicions and further checks should be conducted.

OTHER FACTORS:

- **Did the patient (or did you) notice that the medical product looks, tastes, smells or feels different?** Any irregularity in the uniformity of appearance (colour, shape, texture, size, clarity), flavour, and odour should raise suspicion. For example, the product is discoloured or degraded.
- **Are there any empty or separated packaging components (bottle caps, spoons, bottles, flat packs, capsules)?** Signs of empty or separated packaging components may indicate signs of smuggling or tampering.
- **Was the product properly stored?** Storage conditions (temperature, humidity, etc.) should be stated on the label and maintained. Signs of degradation may include leakage, discoloration, etc.