Substandard and falsified medical product incident management aide memoire

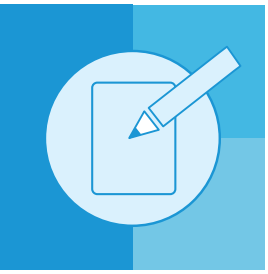
The table below outlines the steps that should be followed in managing substandard and falsified medical product (SFMP) incidents. It is predominantly for use by staff from national health regulatory authorities (NRA) but can, and should be, adapted for use by other public health actors. Any actions should consider national and local context.

[Remember these incidents attract a lot of attention, unnecessary delays are difficult to explain, and public health and the reputation of your organization may be at risk.]

Step	Action
1. SFMP incident is notified 	Identify and contact focal points within your organisation who have been trained to manage SFMP incidents. National health authorities must liaise with the WHO Global Surveillance and Monitoring System on SFMPs. Contact rapidalert@who.int in case of doubt
2. Establish facts 	It is essential to: • Contact the source of the information. • Assess the reliability of the source (see notes on next page). • Assess the credibility of the information received (see notes on next page). • Document any available information and list outstanding questions (consider the "what, when, where, how, why" approach). • Obtain evidence (e.g. product samples and photographs).
3. Identify and assess risks 	The public health risk must be identified and assessed as soon as possible to determine the appropriate response and resources to be deployed. Please also consider the separate documents: *Prioritization and risk parameters,* and *Questions to consider when assessing risk*. Consult with the stated manufacturer of the reported product (see notes on next page).
4. Immediately protect public health 	Once risks are identified, public health must be protected by removing the source of the risk represented by the SFMP. This include the following immediate actions. • Quarantine or seize any suspected medical product dependent on risk. • Ensure the product is stored securely and in compliance with storage conditions. • Ensure appropriate treatment is available for affected patients.
5. Control quality 	The composition of the product may present additional risks to health. Use field screening devices or laboratory analysis to identify appropriate mitigation actions such as replacement treatements (see notes on next page).
6. Coordinate mitigation actions 	To efficiently respond to SFMP incidents, consider the following actions. • Establish a team of relevant regulatory specialists, appoint a lead person and invite relevant external stakeholders/experts. • Keep strict records of all meetings and all decisions that are made. • Focus on protection of public health, mitigating the risk posed by the product and investigating the origin. • Consider a recall of the medical product and issuing associated communications and media messages (e.g. alerts or public notices). • Verify stocks/availability of genuine (quality-assured) replacement product.

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

World Health Organization



Notes to health care professionals

Health and care providers are encouraged to identify national focal points who can conduct a search of the WHO Global Surveillance and Monitoring System database when dealing with a suspected SFMP at the earliest opportunity.

Irrespective of whether there is a match with other products in the database, the suspected or confirmed medical product should be reported to WHO as soon as possible. Other Member States may be seeing the same product in circulation and this report will assist them.

Remember that search results can match with your product on a separate continent or in another region. This information will help you assess risk, manage and respond to your incident more efficiently and effectively, and, in serious cases, save lives.

Assessing the reliability of a source

Reasonable efforts should be made to validate anonymous info information.

- Is the source of the information a whistle blower or a current or ex-employee of a company they are reporting? Yes ☐ No ☐
  - What is the motivation for supplying the information? Yes ☐ No ☐
  - Is the source easily contactable? Yes ☐ No ☐
  - If contact details are supplied, are they accurate (e.g. dialling codes, telephone numbers, email addresses and physical addresses)? Yes ☐ No ☐
- Has information been received from the same source previously? If so, was it accurate? Yes ☐ No ☐
- Is the source willing to be contacted and met, or to supply further information? Yes ☐ No ☐

Assessing the credibility of the information

- Can the product registration number be verified through a national regulatory authority register? Yes ☐ No ☐
- Has any similar information been received from different sources? Yes ☐ No ☐
- Are there any other sources that can corroborate the information provided? Yes ☐ No ☐
- Is there an approved package insert on the national regulatory authority/ manufacturer website? Yes ☐ No ☐
- Are there any obvious inaccuracies in the information? Yes ☐ No ☐

Questions to manufacturers

- Did you manufacture this product? If yes, does the product and packaging look genuine? Photographs and samples should be provided if available.
- Are the manufacturing/batch/expiry dates authentic? If the batch number is genuine, where and when was it distributed?
- Have you had falsified or substandard versions of this batch reported previously? If so, when and where?
- Have you received any complaints about this batch? If so, from whom, where and when?
- Have you received any reports of unexpected adverse reactions relating to this product or batch? If so, when, where, how many and how severe?
- Is there any other information we should be aware of?

Laboratory analysis considerations

- If the product is suspected of causing serious adverse reactions, send samples directly to the laboratory.
- Screen product with handheld screening equipment or other field testing equipment if available.
- Secure as many samples as possible from the same source as the reported product and store in controlled conditions.
- Request samples from genuine manufacturers for comparison purposes.