World Health Organization | Substandard and Falsified Medical Products Incident Management – Aide Memoire

1 Receipt of Report

- Report of SF medical product received by National Medicines Regulatory Authority

2 Establish Facts

- Contact the source of the information
- Assess the reliability of the source (See overleaf)
- Establish the facts
- Assess the credibility of the information received (See overleaf)
- Obtain samples of the product and photographs showing batch number and expiry dates
- ➢ NATIONAL FOCAL POINT FOR SF MEDICAL PRODUCTS SHOULD IMMEDIATELY SEARCH THE WHO GLOBAL SURVEILLANCE AND MONITORING DATABASE TO CHECK IF THE PRODUCT IS KNOWN

3 Assess the Risk to Public Health

- Is the suspected SF product available in hospitals, clinics, pharmacies, health centres?
- Is the product available in illegal markets, or through internet sites or smartphone applications?
- Have any adverse reactions been reported / Check with National Pharmacovigilance Centre?
- What quantities of suspected SF medical products have been discovered?
- Is there evidence that the suspected SF medical product is in recent circulation?
- Is the suspected SF medical product in wide circulation within your country , or neighbouring countries ?
- Is this product in strong demand, or in short supply?
- Consult with the stated manufacturer of the reported product (see overleaf)

4 Immediate Actions to Protect Public Health

- 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 to an affected patients

5 Field Screening and Laboratory Analysis

- If product is suspected of causing serious ADR's send samples directly to the laboratory
- Screen suspected SF product with hand held screening equipment or other field testing equipment if available
- Secure up to 100 samples for testing, if not as many samples from the same source as the reported product as possible and store in controlled conditions
- Request sample from genuine manufacturer for comparison purposes
- Arrange for testing as a priority dependent on risk to public health

6 Managing an Incident Involving a Suspected SF Medical Product

- 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 associated communications and media messages
- Verify stocks/availability of genuine (quality assured) replacement product
- Consider an alert or public notice
- REPORT TO THE WHO GLOBAL SURVEILLANCE AND MONITORING SYSTEM FOR SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS

REMEMBER. THESE INCIDENTS ATTRACT A LOT OF ATTENTION, UNNECESSARY DELAYS ARE DIFFICULT TO EXPLAIN, PUBLIC HEALTH AND THE REPUTATION OF YOUR ORGANIZATION MAY BE AT RISK.

National Focal Points are strongly advised to conduct a search of the WHO database when dealing with a suspected SF medical product at the earliest opportunity.

Irrespective of whether you receive a match with other products in the database you should report the suspected or confirmed medical product to WHO as soon as possible. Other Member States may be seeing the same product in circulation and your report will assist them. It should be remembered searches can yield matches with your product on a separate continent or in another region. This information can help you risk assess, manage and respond to your case more efficiently and effectively and in serious cases save lives.

Assessing the Reliability of a Source

- Anonymous information should be treated with caution
- Is the source a whistle blower or a current or ex-employee of a company that they are providing information about?
- What is the motivation for supplying the information?
- Is the source easily contactable?
- If contact details are supplied are they accurate (dialling codes, telephone numbers, email addresses, physical addresses)?
- Has information been received from the same source previously?
  - If so was the information accurate?
- Is the source willing to be contacted, met, or supply further information?

Assessing the Credibility of the Information

- Has any similar information been received from different sources?
- Is there any other sources that can corroborate the information provided?
- Are there any obvious inaccuracies in the information?

Questions to Manufacturers

- ☑ Did you manufacture this product?
  - Does the product and packaging look genuine? – photographs and samples will 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, numbers, and severity?
- ☑ Is there any other information we should be aware of?