Definitions

SUBSTANDARD
Also called ‘out of specification’, these are authorized medical products that fail to meet either their quality standards or their specifications, or both. e.g. Manufacturing error, expired or degraded

FALSIFIED
Medical products that **deliberately/fraudulently** misrepresent their identity, composition or source.

UNREGISTERED / UNLICENSED
Medical products that have not undergone evaluation and/or approval by the NRRA for the market in which they are marketed/distributed or used, subject to conditions under national or regional regulation and legislation.

Source: [https://www.who.int/medicines/regulation/ssffc/definitions/en/](https://www.who.int/medicines/regulation/ssffc/definitions/en/)
African Customs Seizure

Customs agents conducting a routine search of a cargo shipping container found this inside...

- **Coartem** – Anti malarial
  - 1,383,528 packs

- **Postinor 2** – Emergency Contraceptive
  - 4930 packs

- **Vermox** – Worming treatment
  - 1534 packs

- **Clomid** – Fertility treatment
  - 36,550 packs

- **Clamoxyl** – Antibiotic
  - 744 packs
European Customs Seizure

Customs agents intercepted these shipments of separated packaging components at the airport...

1 million empty capsules

Disguised as Ceylon Stevia Sweetener

1 Manual Capsule-Filling Machine + 1 Carton-Folding Machine
- 31 Jan: rabies vaccines
- 31 Jan, 21 Feb: leukemia treatment traded globally
- 21 Mar: oral cholera vaccines
- 28 Mar: meningitis vaccines
- 16 Apr: contaminated antihypertensive
- 24 Apr: leishmaniosis treatment

Source: https://www.who.int/medicines/publications/drugalerts/en/
**WHO Global Alerts**

**Risk Communication**

- Therapeutic use
- Where and when discovered
- Product specific
- Batch Specific
- Manf and exp dates
- Clarify if falsified or substandard

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**Clear photos**
- secondary packaging
- WHO guide on taking good photos

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**Accurate Information, Advice and Reassurance**

- Advice to patients and health care workers
WHO Estimates 2017*

*Limited to medical products for human use

10.5%

Observed failure rate of analysed medical product samples from low and middle-income countries

US$ 30.5 Billion

Estimated spending on SF medical products in low and middle-income countries based on un-weighted estimates of pharmaceutical sales

Causes

CONSTRAINED ACCESS TO MEDICINES

WEAK TECHNICAL CAPACITY

Limited awareness
Poor oversight
Lack of resources

POOR GOVERNANCE PRACTICES

Unethical practice
Corruption
Poor procurement practices

SF

Availability
Acceptability
Affordability
Consequences

- Lost Productivity
- Lost Income
- Lack of Social Mobility
- Increased Poverty
- Economic Loss
- Wasted Resources
- Increased Out-of-Pocket Spending
- Higher Disease Prevalence
- Progression of Antimicrobial Resistance
- Loss of Confidence
- Increased Mortality and Morbidity (Adverse Effects)

SUBSTANDARD AND FALSIFIED PRODUCTS
WHO Response

POLITICAL RESPONSE

- Member State Mechanism
  - Political support
  - Promote access to affordable, safe, efficacious, and quality medical products
  - Effective Member States’ collaboration and coordination

OPERATIONAL RESPONSE

- Global Surveillance and Monitoring System
  - Immediate technical and operational support
  - Regulatory capacity building and policy guidance
  - Improve current knowledge for in depth analyses, landscape, etc.

PROTECT PUBLIC HEALTH
WHO Member State Mechanism

**MANDATE**

World Health Assembly 65.19 ; 2012

Recognised as an unacceptable threat to public health

**PURPOSE**

International collaboration from a public health perspective on substandard and falsified medical products

**GOVERNANCE**

- Steering Committee
- 1 Chair (India)
- 11 Vice Chairs
- Regional Rotation
<table>
<thead>
<tr>
<th>2018-19 Prioritized Activities</th>
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<td>As agreed by the Member State Mechanism</td>
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</table>

- Develop and promote training material and guidance documents for the prevention, detection and response to SF medical products
- Expand and maintain the global focal point network among national medicines regulatory authorities
- Improve understanding of detection technologies, methodologies, and “track and trace” models
- Increase knowledge of links between SF medical products and access to quality, safe, efficacious and affordable medical products
- Develop and leverage risk communication and awareness campaigns
- Expand awareness, effectiveness, impact and outreach
- Promote understanding from a public health perspective regarding medical products in transit
- Identify strategies for the distribution or supply of SF medical products via the Internet
WHO GLOBAL SURVEILLANCE and MONITORING SYSTEM

Available in English, French and Spanish

150 Member States trained
700+ Regulatory Personnel trained
18 Large Procurement Agencies sensitized
3 Languages for reporting and response
28 Training Workshops in all regions

111+ Countries reported incidents
2000+ Reports of suspect products
28 Global Drug Alerts (+ warnings and regional bulletins)
WHO Technical Assistance in 100+ cases
Landmark report in 2017
What to Report

Medical products stolen from public aid or humanitarian programmes

Unexpected adverse reactions, particularly a lack of efficacy

Falsified or seriously substandard products (suspected or confirmed)
When to Report

The product and batch may have already been reported by another Country.

The risk to public health may have already been assessed.

Report suspicion early and search the WHO Portal.

The suspicious product may have already undergone laboratory analysis which can be shared.

Another country may be investigating the origin of the product and have helpful information.
Who Reports

Terms of Reference for Global Focal Point Network

- Situated within the National Medicine Regulatory Authority
- Empowered to closely cooperate with relevant government entities
- Trained on the use of the WHO GSMS
- Empowered to receive and respond appropriately to all alerts

1 Global Focal Point Network Terms of Reference: http://www.who.int/medicines/regulation/ssffc/mechanism/A69_41-en6-8.pdf?ua=1
Coordination and Collaboration

WHO Global Surveillance and Monitoring System for substandard and falsified medical products

Regional Rapid Alert Network

National risk based post market surveillance and reporting systems
How to Report

1. Via secure online portal, which is also used to search the database and access training material

2. Offline reporting form in Excel and email to WHO
WHO GLOBAL SURVEILLANCE and MONITORING SYSTEM

1. Focal Point sends Report
   Auto receipt sent from WHO

2. Automatic email
   notification to WHO

3. Report uploaded and
   translated in database

4. Internal risk assessment for
   prioritization

5. Immediate
   link to similar
   reports

6. Validate Data and
   Technical support

7. WHO medical product
   alert and other
   necessary action

8. Classification &
   Closure
<table>
<thead>
<tr>
<th>Year</th>
<th>Overview of SF Veterinary Product Reports Received</th>
</tr>
</thead>
</table>
| 2017 | 1. Substandard Canigen LR rabies vaccines in France  
2. Falsified Trisulfon powder in Ukraine  
3. Falsified Neostomosan concentrate in Hungary  
4. Substandard Tylosin 20 H in Germany  
5. Substandard Cefshot DC in the UK  
7. Substandard Deparvax/Deparmune in Hungary, Poland and France  
8. Substandard Avinew Neo vaccines in France  
9. Substandard Colistina Solfato in Czech Republic  
10. Substandard Amoxinfect in Germany  
11. Falsified Biocan R rabies vaccines in Poland  
12. Substandard Avilosin in the UK  
13. Unregistered Nifuramycin Powder in Germany  
14. Substandard Narcostop in Hungary |
| 2018 | 1. Substandard Oxytoxin in Germany, EU countries, Serbia, Egypt, UAE, Cuba and Sri Lanka  
2. Contaminated Overvac EC in Spain  
3. Substandard Lactaclox Intrammary Infusion in the UK  
4. Substandard Willcain in the UK  
5. Substandard Bovigam Lactacion in Spain  
6. Suspension of Diethanolamine in the Netherlands  
7. Substandard Vectormune ND vaccines in Hungary  
8. Substandard Norocarp in Spain  
9. Substandard Oxyvet 100 LP in Barbados and Jamaica |
| 2019 | 1. Falsified Micotil in the UK  
2. Stolen Eravac, Eryseng Parvo PET, Suiseng PET, and Vepured Pet in Denmark  
3. Substandard Meloxidolor in Spain  
4. Substandard Anaestamine in Czech Republic, France and UK  
5. Substandard Media Fill Simulation for Suite 11 Aseptic Manufacturing System 1 in UK, Croatia and France  
6. Substandard Norocarp, Enrotril, Noromectin, Alamycin, and Paramectin Injectable in Spain  
7. Substandard Pyceze  
8. Substandard Carprosan in Spain |
<table>
<thead>
<tr>
<th>Lessons Learned</th>
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<tbody>
<tr>
<td><strong>From global policy to local impact</strong></td>
<td><strong>POLITICAL WILL</strong> is required to translate policy agreed at the global level to <strong>SUSTAINABLE ACTIONS</strong> on the ground with <strong>APPROPRIATE FINANCIAL AND HUMAN RESOURCES</strong></td>
</tr>
<tr>
<td><strong>Sound investment strategies</strong></td>
<td><strong>STRENGTHENING REGULATORY CAPACITY AND SYSTEMS</strong> is a key step and <strong>SOUND INVESTMENT</strong> to safeguard the manufacture, distribution and supply of medical products</td>
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<tr>
<td><strong>Cooperation and coordination</strong></td>
<td>Improved <strong>REPORTING SYSTEMS</strong> and greater <strong>TRANSPARENCY</strong> within and between countries is required, together with wide and <strong>EFFECTIVE MULTI STAKEHOLDER ENGAGEMENT</strong></td>
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</table>
Diana Lee
Technical Officer, Substandard and Falsified Medical Products Group
leedi@who.int / rapidalert@who.int