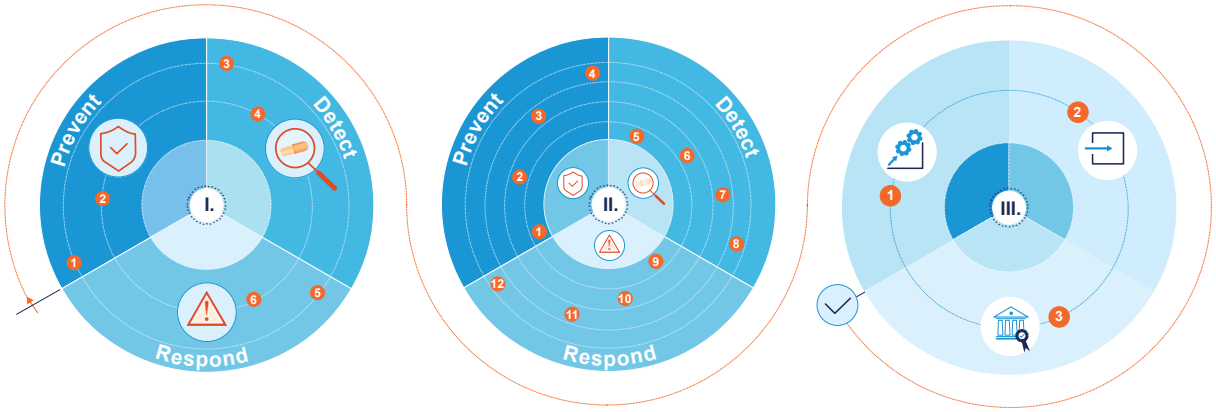
WHO prevent–detect–respond strategy to combat SFMPs



I. Objectives

Prevent
1. Demand quality
2. Secure supply

Detect
3. Improve detection
4. Increase reporting

Respond
5. Protect public health
6. Prevent recurrence

II. Actions

Prevent
1. Supply chain integrity
2. Education and awareness
3. Multi-stakeholder engagement
4. Comprehensive legal framework

Detect
5. Border control
6. Reporting system
7. Risk-based inspection and surveillance
8. Access to laboratories and screening technologies

Respond
9. Alerts and recalls
10. Regulatory strenghtening
11. Transparent legal process
12. Evidence-based policy and procedure

III. Impact

Safety and quality
1. Increased technical capacity
2. Improved access
3. Strengthened governance

Prevent

Supply chain integrity

A track and trace system with an authentication process has been implemented for medical products.

The supply chain has been mapped from point of manufacture or importation through to public outlets, pinch points identified and staff trained to identify, report and respond to suspected substandard and falsified medical products.

Education and awareness

There are focused education, media and awareness programmes, for non-health professionals, the general public and civil society groups on substandard and falsified medical products.

The issue of substandard and falsified medical products is integrated as part of the core medical, pharmacy and regulatory curriculum.

Multistakeholder engagement

There is clear and regular communication with civil society groups, health care professional organizations, the pharmaceutical industry and actors within the supply chain, specifically focusing on substandard and falsified medical products.

There are documented and implemented procedures for regular engagement with the relevant government departments and agencies, including national pharmacovigilance centres, national poison centres and national quality control laboratories.

Comprehensive legal framework

There are legal provisions in place enabling the national medicines regulatory authority (NMRA) to seize, quarantine, sample, analyse, recall and destroy substandard and falsified medical products.

There are legal provisions in place for the inspection, investigation, enforcement and proportionate sanctioning of those engaged in the manufacture, distribution, storage, supply and sale of substandard and falsified medical products.

There is a documented strategy and guidelines in place and implemented relating to the prevention, detection and response to substandard and falsified medical products.

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

World Health Organization

Detect

Border control

There are designated ports for the importation and export of medical products, and a regulatory presence at those ports.

There are documented and implemented procedures for allowing the exchange of information concerning suspected substandard and falsified medical products between customs, police and the regulatory agency.

Reporting systems

Effective public reporting systems exist, enabling the reporting of suspected substandard and falsified medical products and adverse drug reactions to the NMRA.

Risk-based inspection chains and surveillance

A risk-based strategy is documented and implemented for conducting regular targeted and random market surveillance for substandard and falsified medical products within the regulated and unregulated supply

There is a documented and implemented risk-based inspection programme for those entities engaged in the manufacture (including relabelling/repackaging), importation, distribution/ wholesale and supply/sale of medical products.

Access to laboratories and screening technologies

There is access to an externally accredited national quality control laboratory and documented procedures are in place and implemented regarding the analysis and reporting of substandard and falsified medical products.

There is access to field screening equipment (and relevant reference material), which staff have been trained to use, and procedures are documented and implemented for the use of such equipment.

Respond

Alerts and recalls

A documented and implemented procedure exists concerning the issuing, receipt and response to Rapid Alerts concerning substandard and falsified medical products.

A designated and trained focal points) within the NMRA has been established to receive and respond to reports of suspected substandard and falsified medical products and has access to the WHO Global Surveillance and Monitoring System for substandard and falsified medical products.

Regulatory strengthening

Regulatory personnel are designated and trained in the response to substandard and falsified medical products and documented procedures have been established and implemented.

The prevention, detection and response to substandard and falsified medical products has been embedded in core regulatory responsibilities across departments and government agencies and is included in regulatory assessment indicators.

Transparent legal process

The use of regulatory or criminal law sanctions is justified and applied in a consistent and proportionate way. The application and use of sanctions is published by the national or regional regulatory authority.

Evidence-based policy and procedure

Each incident involving substandard and falsified medical products has been reviewed with a view to identifying weaknesses in the system, vulnerabilities in the supply chain and making appropriate changes to improve the safety of patients.

There is clear use of data from a wide range of sources in developing evidence-based policy and procedures to prevent, detect and respond to substandard and falsified medical products.

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products

For further information, please visit our website: www.who.int/medicines/regulation/ssffc/en/

Source: WHO, 2017.