3.3 Module C. Detect

Module overview

Module C introduces how to detect SFMPs. It covers the detection methods and tools, and includes product identification, regulatory action, pharmacovigilance and global marketing surveillance of SFMPs.

Learning objectives

At the end of Module C, learners in levels 1, 2, and 3 should be able to demonstrate the competencies (knowledge, skills and attitudes) outlined in Tables 24, 25 and 26. **Note.** Level 2 learners must demonstrate competency in the elements of levels 1 and 2, while level 3 learners must demonstrate competency in the elements of levels 1, 2 and 3.

Table 24. Level 1: health services providers' knowledge, skills and attitudes competencies

Competency	Ability
Knowledge 	• Explain how detection strategies complement, and do not replace, prevention strategies. • Identify the different levels of the supply chain where detection of SFMPs is relevant (from manufacturing to the use of medical products). • Differentiate between screening technologies and confirmatory laboratory analysis. • Describe the roles and responsibilities of various stakeholders in detecting SFMPs throughout the supply chain and outside it, in particular their own role at point of care. • Summarize the different regulatory strategies related to detection and how they complement each other (e.g. inspection, market surveillance and pharmacovigilance). • Give examples of the different type of analysis that can be done for quality control of a medical products (visual, physical and chemical). • Describe the role of visual inspection along the supply chain and at the point of care. • Give examples of the main advantages and limitations of field detection technologies for quality control and traceability.
Skills 	• Perform appropriate visual inspection of medical products using a checklist. • Follow GSDP to detect SFMPs. • Promptly and accurately report suspected cases of SFMPs to appropriate local/national authorities.
Attitudes 	• Recognize the relevance of detection strategies in their own (future) professional life. • Demonstrate commitment to following procedures and guidelines to detect and report SFMPs. • Consider their future participation in detecting SFMPs as a positive opportunity for holistic care, rather than an extra burden. • Proactively communicate to colleagues and patients about visual inspection and GSDP. • Proactively communicate to colleagues and patients about surveillance and pharmacovigilance to enhance field and community reporting.

GSDP: good storage and distribution practice; SFMP: substandard and falsified medical product.

Table 25. Level 2: health management personnel's knowledge, skills and attitudes competencies

Competency	Ability
Knowledge 	• Discuss (e.g. objectives and principles) the different regulatory strategies, namely, pharmaceutical control and inspection, market surveillance, pharmacovigilance and quality control. • Critically assess national and local application/implementation (strengths and weaknesses). • Discuss the advantages of and limitations to methods for detecting SFMPs as well as those associated with the use of portable quality control devices. • Describe the different analytical methods used for quality control.
Skills 	• Propose and design SFMP organizational detection plans. • Incorporate detection of SFMPs in operational procedures of distributors, wholesalers or retailers. • Apply market surveillance and pharmacovigilance in their own working environment. • Assess the applicability, or not, of field detection and traceability technologies in their own working environment, including research when applicable. • Communicate adequately about the complexity of detection strategies.
Attitudes 	• Be aware that/how detection strategies should be built in their programme/organizations. • Encourage colleagues, team members and hierarchy to support detection of SFMPs. • Promote the use of visual inspection and GSDP at their own organizations. • Advocate for funding to strengthen GSDP. • Promote development of joint educational and awareness campaigns on SFMP detection. • Promote a reporting culture to increase reporting of SFMPs.

GSDP: good storage and distribution practice; SFMP: substandard and falsified medical product.

Table 26. Level 3: regulators and policy-makers' knowledge, skills and attitudes competencies

Competency	Ability
Knowledge 	• Master the use of track and trace technologies such as block chain, serialization and authentication systems that can help track and verify the authenticity of medicines throughout the supply chain, detect irregularities and prevent the entry of SFMPs.
Skills 	• Sensitize policy-makers on the importance of detection. • Provide training on how to incorporate SFMP detection in procedures of a distributor, wholesaler or retailer. • Provide training on different regulatory functions related to detection and how they are complementary.
Attitudes 	• Influence the incorporation of strategies to detect SFMPs in national health policies. • Adopt a public health approach in the detection of SFMPs by avoiding confusion with issues of intellectual property rights. • Value the equally essential role of all actors along the supply chain to detect SFMPs. • Advocate for the strengthening of good storage and distribution practices in national health policies.

SFMP: substandard and falsified medical product.

Recommended learning activities

- Allocate sufficient time for this module (about 4 to 8 hours) for practical exercises and discussions.
- Ask learners to create a poster or equivalent visual/narrative description of the country pharmaceutical sectors and of the manufacturing and supply chain; and to indicate the possible detection methods and at which level of the supply chain they would work. Ask other learners to provide constructive feedback on their efforts in relation to the knowledge, skills and attitudes.
- Plan a group work exercise. Give each group one or more examples of a WHO Medical Product Alert or case from the scientific literature covering different scenarios of SFMPs to review. The exercises should be based on real and documented cases. For instance, the Gambia syrups incident in 2022 is well documented and offers a good basis for developing a practical exercise on substandard medical products. If possible, ask the NRRA to provide examples of SFMPs detected and withdrawn from the local market and additional information relevant to the country.
- Present, if possible, tools and guidelines used in inspections and field screenings of medical products, including visual inspection checklists and, if available, portable screening devices.
- Plan practical exercise for visual inspection. Ask trainees to perform visual inspection (using a visual inspection checklist) of potential SFMPs (e.g. from the informal market) and to detect the items that do not conform with the real product. Make use of a few examples with photographs (always available in the WHO Medical Product Alerts).
- Organize practical laboratories to allow testing and practice different detection tools (according to availability), especially for those involved in detection.
- Ask learners about the benefits, means and challenges of post-registration monitoring.
- Highlight the need to coordinate the work of different stakeholders (e.g. NRRAs, manufacturers, suppliers and regulatory harmonization initiatives and health insurance organizations)

3.3.1 Detection of SFMPs throughout the supply chain

Where and when can SFMPs be detected

SFMPs can be detected at any level of the supply chain and by any actor in the health/pharmaceutical systems.

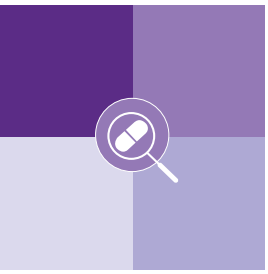
Suspected SFMPs can be detected using a range of approaches, including routine inspections performed by national or regional authorities and enforcement agencies, targeted risk-based surveys, investigation of complaints, follow-up of reports on any suspicious observations in the supply chain, discrepancies during verification, and investigation of unexpected adverse events reported to have occurred with a specific product. It is important to evaluate any information on SFMPs reported by customs, medicines inspectorates and other authorities, procurement agencies, wholesalers and importers, pharmacies, health care institutions, patients and other stakeholders.

Systematic surveillance and appropriate controls are required at all levels of the supply system to detect quality problems when prevention fails. Ideally, SFMPs should be detected as early as possible during production and in the supply chain. Early detection of quality threats such as substandard ingredients, manufacturing errors, breaches in the cold chain, or the detection of unregistered medical products can avoid unnecessary health risks to patients and financial losses.

It is important to note that no detecting technique responds to all needs and the choice of a particular system depends on the local context, access and the final objectives of the analysis, among other considerations.

The result of a screening test is only indicative (preliminary or presumptive adverse analytical result) and other analytical techniques must be applied to confirm unequivocally that a falsified medical product has been detected.

Fortunately, not all SFMPs reach the end-user. It is important to note that when SFMPs do reach the patient, this is an indicator that the quality assurance systems have failed and that structural corrective measures are needed.



It is important to stress that many SFMPs are never detected. In armed-conflict situations and prolonged security crises, for instance, the proportion of SFMPs can be high, but detection and reporting low due to the lack of a supporting health and regulatory system.

All actors in the supply chain may play a role in detecting SFMPs. However, detection strategies, including the use of new quality control technologies, need to be customized to specific users and purposes. Likewise, given the high degree of variability in medical products and sophistication in falsification, no single analytical method can identify all falsified medical products.

There are three different levels of detection

- screening and detection technologies
- technologies for confirmatory testing (only in laboratories)
- forensic testing to determine the origin of manufacture as part of criminal investigations or testing for unknowns in a sample of product.

Forensic testing can be conducted in reference laboratories and is the critical last step in investigating SFMPs. It can lead to the identification and prevention of criminal practices.

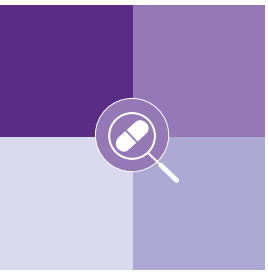
It is important to note that SFMPs can be detected at any level of the supply chain, outside routine controls. This is why it is vital to remain vigilant at all levels of the health system.

WHO regularly develops and updates guidance documents. A forthcoming edition (expected in 2025) will survey the range of screening technologies used to detect SFMPs across a range of criteria, including local context, accessibility and cost, among others.

Roles and responsibilities in the detection of SFMPs

Good collaboration between all stakeholders, clear procedures for identifying quality threats and detecting SFMPs and adequate systems to report suspected SFMPs are all equally essential. The following list describes the role of some key actors.

- **NRRAs** have the highest responsibility for detecting SFMPs through various regulatory activities, including pharmaceutical control (national quality control laboratories), inspection, market surveillance, pharmacovigilance and participation in international surveillance mechanisms. NRRAs should also provide adequate guidance to health care staff, pharmacies, customers and other stakeholders when suspected substandard, deteriorated or falsified medical products are identified at any level of the supply chain.
- **Manufacturers** have a high level of responsibility in ensuring rapid detection of any threats to the quality of manufacturing and identification of defective products before they are sold and distributed. Manufacturers also have standard procedures in place for batch recall (when a quality problem is detected post-marketing) and for implementation of traceability technologies to differentiate authentic medical products from falsified ones.
- **Customs, law enforcement and freight forwarders** can play a key role in detecting suspected SFMPs at the border. Law enforcement also plays a crucial role in identifying and pursuing all illegal markets for medical products, including those sold through the internet.
- **Procurement agencies, suppliers and distributors** all have a role in detecting SFMPs, particularly when procedures have not been respected and quality threats are identified during procurement, storage and distribution activities.
- **Pharmacy managers** (at health care facilities and private pharmacies) can detect suspicious products and prevent the distribution of SFMPs to patients by following applicable norms and procedures.
- **Health care providers** can also help detect SFMPs. For instance, doctors may suspect a quality problem in case of treatment failure or toxicity, and nurses may identify SFMPs during product administration if their appearance is different.



- **Patients and caregivers** can identify SFMPs when they observe that the physical appearance of a medicine, or its effect, is different from usual.
- **All stakeholders** are collectively responsible for avoiding the acquisition and distribution of unregistered/unlicensed medical products, as well as the acquisition and distribution of medical products from illegal sources. All stakeholders should report the sale of illegal medicinal products to the NRRA and/or law enforcement.

3.3.2 Basic techniques for detection of SFMPs

Threats related to storage and distribution

The physical appearance of a substandard medical product may not always show evidence of a quality problem. However, some medical products can quickly deteriorate when stored or transported in inadequate conditions. Distributors and store managers at any level of the health care system should have procedures in place to take action to quarantine medical products that may have deteriorated. They should also have an action plan to assess the risk and implement appropriate response measures.

Poor storage, distribution and transportation practices are a strong indicator of SFMP and the following issues should be considered.

- A breach in the cold chain of heat-sensitive medical products is a serious threat to the quality of the products. Cold-chain breaches can occur due to excessively high or low temperatures. During transportation, the cold chain can be monitored using cold-sensitive devices. During storage, temperature should be monitored and recorded. Verifying temperature records is the first step in detecting possible deterioration of heat-sensitive medical products.
- High temperatures, as well as humidity, can threaten the integrity of medical products. Sometimes, humidity may be visible when it affects the external and/or internal packaging of medicines. However, humidity may not always be visible and can still lead to degradation. In addition to temperature records, humidity records are a first step in detecting possible deterioration of medical products.
- Any packaging deterioration during transportation or storage, due to inadequate handling or accidental exposure to risk, should be identified as a threat to the quality of the products.
- Any expired medical product or one with a remaining shelf-life that cannot guarantee its consumption before the expiry date should be treated as a substandard medical product and be quarantined and disposed of (in line with adequate disposal procedures that are not harmful to the staff and to the environment).
- Quarantine should be made very secure to avoid any theft and introduction of these expired products into the informal market or inadvertent reintroduction into the formal market.

Visual inspection

Visual (or physical) inspection is the first frontline method to detect SFMPs. Procedures and tools used for visual inspection are available from WHO and other relevant stakeholders but should be adapted to the different areas in the supply chain. For instance, visual inspection conducted by manufacturers or a reference quality control laboratory would involve using the most rigorous procedures and technologies, while other actors may follow simplified and less sensitive procedures. Section 5.1 of this toolkit includes WHO guidance on identifying SFMPs.

Procedures for visual inspection at medical stores and central pharmacies of referral hospitals handling large volumes of medical products should be systematically implemented as part of reception procedures. These procedures should consist of physically examining external packaging of all parcels received and inspecting samples from different batches including: primary and secondary packaging; labelling information and appearance; visual aspects, such as odour, colour, and consistency; correct language of inserted leaflet; and security features and other markings (e.g. registration number, CE mark for medical devices and global trade item number) as evidence of marketing authorization.

These measures should be applied using standard operating procedures and tools such as checklists. If possible, the medical products should be compared against samples provided by the supplier.

Simplified procedures for visual inspection can be implemented by pharmacists and other health staff, such as nurses, in any location of the health facility where medical products are available for dispensing or administration to patients, including the pharmacy and stocks at emergency rooms, wards and theatres. Quick routine visual inspections may detect expired products, as well as possible deterioration caused by long storage in inadequate conditions, poor manufacturing of product and/or accidental deterioration. Particular attention should be paid to the physical appearance of injectable medicines before administration, such as sudden changes in colour, unusual separation (e.g. for emulsions and/or the presence of visible particles).

Some agents in direct contact with suppliers of falsified medicines, such as customs or border law enforcement, need to be able to detect falsified medicines quickly by visual inspection and require simplified tools.

All actors in the supply chain should be trained on the possible infiltration of falsified medical products into the supply chain. Subtle and/or evident changes in the appearance of labelling of a medical product, such as differences in ink colour, packaging design, fonts, labelling information (such as origin of the product), or any other deviation from the usual appearance of a medical product should be immediately reported as a possible falsified medical product. Additionally, the lack of key information on the packaging (e.g. registration number, manufacturer name and batch number) can be suggestive of unregistered or falsified products.

3.3.3 Regulatory strategies and laboratory methods for detection of SFMPs

Regulatory functions of NRRAs assure the safety, quality and efficacy of medical products. Detection of SFMPs is closely related to four functions: pharmaceutical control; inspection; market surveillance (including testing); and pharmacovigilance.

Pharmaceutical control

Pharmaceutical control encompasses a broad range of activities and regulatory requirements aimed at ensuring that pharmaceutical products are consistently produced and controlled according to quality standards. It involves the entire life cycle of a product, from development through manufacturing to post-market surveillance.

Pharmaceutical control applies to the manufacturing, import and distribution of chemical or biological raw materials, active ingredients, excipients for pharmaceutical use and finished pharmaceutical products.

The detection of deviations from GMP, GSDP, or other applicable norms and standards may result in regulatory sanctions and penalties. Additionally, it can trigger further investigations and actions, such as involving law enforcement and conducting quality testing of samples.

Within the broader function of pharmaceutical control, **quality assurance** aims to prevent defects from happening in the first place by establishing clear processes, documentation and standards throughout the entire manufacturing process. A subset of quality assurance is **quality control**, which involves the testing and evaluation of materials, components and final products to ensure they meet the necessary specifications and standards. Quality assurance therefore includes the systematic activities and systems to ensure quality is built into the product and processes, while quality control focuses on testing and verifying that products meet required quality standards.

Inspection

Inspections serve a dual purpose: they prevent the manufacturing and distribution of SFMPs (including through deterrence) and detect threats to quality, including the identification of suspected substandard, falsified and unlicensed/unregistered medical products.

Inspections can be conducted regularly, randomly or in response to indications of possible malpractices or misconduct. They include all relevant actors across the supply chain, from manufacturers, importers, wholesalers and distributors to logistic operators, pharmacies and hospital pharmacies.

Market surveillance and testing

Market surveillance by NRRAs focuses on medical products after they have been released and become available on the market. It includes the control of import activities, the monitoring of the quality of medical products throughout the supply chain, and the control of promotion, marketing and advertising activities. This surveillance includes the random or scheduled collection of medical product samples at different stages of the supply chain for quality control purposes. The aim is also to obtain information on SFMP distribution channels and to monitor potential illegal sales channels (e.g. unauthorized markets and internet sales).

Market surveillance comprises active monitoring programmes and approaches that support proactive collection and monitoring of data on medical product quality, safety and efficacy.

Actions conducted by NRRAs in market surveillance may include coordination with other NRRAs and stakeholders such as WHO, customs and law enforcement (at the national or international level) to streamline actions for the detection of SFMPs and illegal markets.

The WHO GSMS collaborates with Member States to improve data and information on SFMPs. The WHO Medical Product Alert system (see section 3.4.3) can be used by NRRAs to target the detection of SFMPs that have been found in other countries.

Market surveillance by regulatory authorities may be a weak point in the system to fight falsified medicines. This is mainly due to a lack of: resources (in particular technical means for centralized reporting); availability of and access to updated regulatory databases; screening and detection technologies; computer equipment; software; and Internet access. In addition, it should be noted that donations of medical products are often not targeted by market surveillance strategies.

Pharmacovigilance

Pharmacovigilance functions are aimed at detecting and analysing adverse effects related to product safety, as well as other problems related to the use of medical products that are legally marketed or otherwise approved for defined clinical use (e.g. medical products used in clinical trials).

Despite the core focus on safety profiles, pharmacovigilance alerts may be prompted due to a quality problem such as chemical or biological contamination. Therefore, pharmacovigilance may also play a role in the detection of SFMPs. This point is crucial, as if an SFMP product is detected but not reported on time to the appropriate stakeholders, it is worthless.

Information used in pharmacovigilance may be provided by patients, and through clinical observations, epidemiology studies, clinical trials and pharmacovigilance data. All actors involved in generating such data should be informed about pharmacovigilance reporting systems and encouraged to report any suspect cases.

Manufacturers

Manufacturers need to implement high-standard quality control and quality assurance during the manufacturing process and for finished pharmaceutical products before authorizing the batch release.

NRRAs

Quality control laboratories of medical products can be part of NRRAs or may be independent public or private structures. In any case, NRRAs need access to high-standard and well equipped quality control laboratories (ISO 17025 and/or WHO prequalified) to verify the quality compliance of raw materials and finished pharmaceutical products.

Laboratory analysis by the NRRA may be required in routine pharmaceutical activities such as batch release of vaccines and marketing surveillance. During routine laboratory analysis, SFMPs may be detected. Laboratory analysis may also be required to investigate suspected SFMPs, for example, as a result of visual inspections and pharmacovigilance.

Control procedures

Wherever appropriate, pharmacopoeial methods and specifications should be used. Pharmacopoeias establish the minimum standards and methods of analysis to determine the quality of finished pharmaceutical products, including quantitative determination of active ingredients and contaminants. Monographs for medical products may be available in more than one pharmacopoeia and may differ by manufacturer, which therefore requires consideration of the different methods and specifications to expose quality problems.

The types of analysis that can be conducted at a quality control laboratory include:

- visual analysis such as inspection of packaging integrity, labelling, dosage units, and/or various product security features, for example, holograms and microprinting;
- physical analysis such as evaluating product hardness, density, uniformity of dosage units, particle size, disintegration, dissolution performance, refractive index, or physical characteristics under a microscope;
- chemical analysis (providing the most direct supporting evidence in favour of or against a product's quality through, for example, assay of impurities and related substances), such as examining a product via spectroscopy (e.g. ultraviolet, infrared and nuclear magnetic resonance), spectrometry, chromatography, capillary electrophoresis and wet chemistry;
- microbiological analysis to determine the microbial contamination or sterility of medical products (this can also be conducted on non-sterile products).

Quality control compliance or non-compliance is documented in certificates of analysis that laboratories and manufacturers deliver as proof of the analyses conducted.

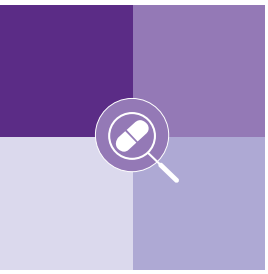
3.3.4 Field technologies for quality control and tracing of medical products

Portable quality control devices

Quality control analysis conducted in reference laboratories can be expensive and the results may take time. Access to quality control laboratories is not always easy and, in some countries, reference quality control laboratories are absent, necessitating additional time and costs for international freight. In the recent past, various portable screening and detection technologies have been developed, which offer the possibility of conducting some rapid quality control tests at the field level to screen out SFMPs. When used appropriately, these devices greatly increase the number of samples that can be screened out which reduces the number of samples requiring more resource intensive confirmatory testing at quality control laboratories that meet international standards.

All portable quality control technologies have advantages and limitations and cannot produce results comparable to the analysis conducted in reference laboratories. The following factors should be considered when acquiring or using these technologies.

- What is the capacity of the user to conduct the analysis, as well as their training and supervision needs?
- What is the capacity of the user to interpret the results and act accordingly? Generally, results indicating that the test has not identified a quality defect do not necessarily mean that the product is of good quality. However, if the test detects a quality defect, it is more likely that the product is an SFMP.
- What is the range, number and type of medical products that can be analysed with a particular device? For example, some devices may have been designed for only one type of medicine (e.g. antimalarials), while some pharmaceutical forms can be long and complex to complete.



- Is there a need for sample preparation?
- What are the characteristics of the technology? Some devices can perform qualitative and quantitative analysis; some destroy the medical product while others do not.
- What is the need for consumables, reagents and reference libraries?
- What is the price, portability, complexity and need for maintenance and other (indirect) costs?
- What environmental conditions can affect the performance of the devices?

Portable quality control devices may be useful for screening purposes (particularly during inspections and market surveillance conducted by NRRAs), at the first stage of quality surveys conducted for research purposes, and potentially by law enforcement and customs officers.

Some examples of portable devices available in the market include:

- near-infrared scanners
- rapid diagnostic tests using lateral flow immunoassays
- paper analytical devices using paper-based colorimetry
- Raman spectroscopy
- paper-based microfluidics detection technology
- sample illumination at specific wavelengths
- photometric devices using fluorescence
- thin-layer chromatography.

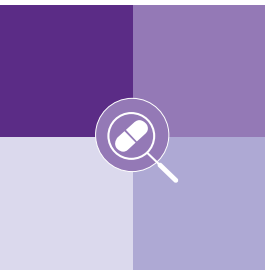
Tracing systems

Tracing systems are used to trace medical products along the supply chain – from manufacture to the point of dispensing. Tracing systems can provide visibility of medical products by:

- ensuring only authorized products, registered or approved, circulate in the legal supply chain;
- preventing the distribution and/or dispensing of falsified, expired, prohibited or recalled products;
- facilitating efficient market recalls;
- enabling efficient inventory management at all levels; and
- identifying shortages and monitoring the reasons for shortages and stock-outs.

There are nine common features of tracing systems which rely on an existing regulatory system, national resources and local context:

- identification (product master data, e.g. product name, active ingredient, strength and packaging);
- use of global standards (enabling standardization and interoperability between traceability systems);
- lot/batch-level traceability (enabling batch-level recalls);
- unit-level serialization (a unique serial number in combination with product code on every saleable unit);
- aggregation data (required with serialization of multiple levels of packaging);
- verification (determining validity of unique identifiers on a product);
- full track and trace versus point of dispensing verification in order to detect falsified products immediately before dispensing (track is defined as the "the ability to know where a product is right now", while trace is the "ability to know where a product has been within a supply chain prior to its current location") *(26)*;



- patient verification (checking authenticity by comparing product identifiers to corresponding master data held in a central repository);
- detection and response, including reporting.

Data and coding standards are essential. Data carriers include barcodes (linear or two-dimensional data matrix) and radio frequency identification tags that comply with data exchange standards. Generally, the subject of global standards, data exchange in this context, refers to the sharing and/or movement of structured data from one party to one or more parties, based on advanced agreement on the structure and data transmission protocol *(27)*. Tracing requires certain data (product code, batch number and expiry date) to be present on the label in both a human readable format and on the data carrier. However, this alone will not detect falsified medical products entering the supply chain; rather, this will track where batch numbers are for recall purposes. Tracing at the unit level requires serialization which is more useful for detecting falsified medical products.

The following are some of the main track and trace technologies.

- Authentication systems. Authentication systems are technologies and processes designed to verify the authenticity of a product. These include tamper-evident packaging, holograms and digital markers that can be scanned to confirm that a product is genuine.
- Block chain. Block chain is a decentralized, distributed ledger technology that records transactions across many computers in a way that ensures the records cannot be altered retroactively. This helps in tracking the entire journey of the product, ensuring its authenticity and preventing the introduction of SFMPs.
- Serialization. Serialization assigns a unique identifier, usually in the form of a serial number, to each individual unit of a product. In the pharmaceutical industry, this means that each package of medication is given a unique code that can be tracked throughout the supply chain.
- Tamper-evident packaging. This packaging designs shows clear evidence if a product has been tampered with. Examples include security seals, shrink bands and blister packs. Tamper-evident packaging helps ensure that medicines have not been altered or contaminated after they leave the manufacturer, thus providing an additional layer of security in the supply chain.

3.3.5 Internal controls and internal reporting

All manufacturers, importers, wholesalers and distributors should have in place internal controls and reporting channels as part of the quality assurance system, in line with WHO GMP and model quality assurance system guidelines.

- SFMPs can represent failures in both quality and safety. This means there cannot be safety without quality. Some quality threats may be handled internally and may simply require the elimination of the out-of-specification products; for example, in cases where a quality problem is detected during production, the batch can be disposed of.
- Some quality threats need to be reported to the NRRA for further action. This may happen, for example, if the suspected or confirmed SFMP batch is already released and has been distributed directly or through other suppliers; or if a distributor realises that they have been supplied with a suspected falsified or unlicensed product.

Health care staff at all levels of the health system should be trained to immediately report to the pharmacy and/or medical director or relevant supervisor any suspected SFMP, for instance in case of:

- suspected toxicity or side-effects or lack of therapeutic efficacy
- unusual numbers of positive or negative results for diagnostic tests
- suspected quality issues, for example, due a change in the product's physical appearance.

Such cases should be internally reported for the implementation of adequate responses, including quarantining and withholding use in the health facility, as well as timely reporting to the NRRA, the pharmacovigilance systems, the supplier or the manufacturer. The health facility management should create an institutional culture of precautionary reporting, where staff are not afraid of being blamed for redundant reporting.

Reporting obligations and procedures should be the same across the public, private and non-for-profit private sector. For instance, private pharmacies should apply the established regulatory procedures to immediately report suspected SFMPs to the NRRA, as well as any suspected adverse reactions by the patients for further investigation.

© WHO / Volodymyr Shuvayev

Checkpoint crossing.


© WHO

Customs' inspection of medical supply shipment.


© WHO / Christopher Black

WHO logistician doing an inventory.


© WHO / Christopher Black

Inventory of a storage site.