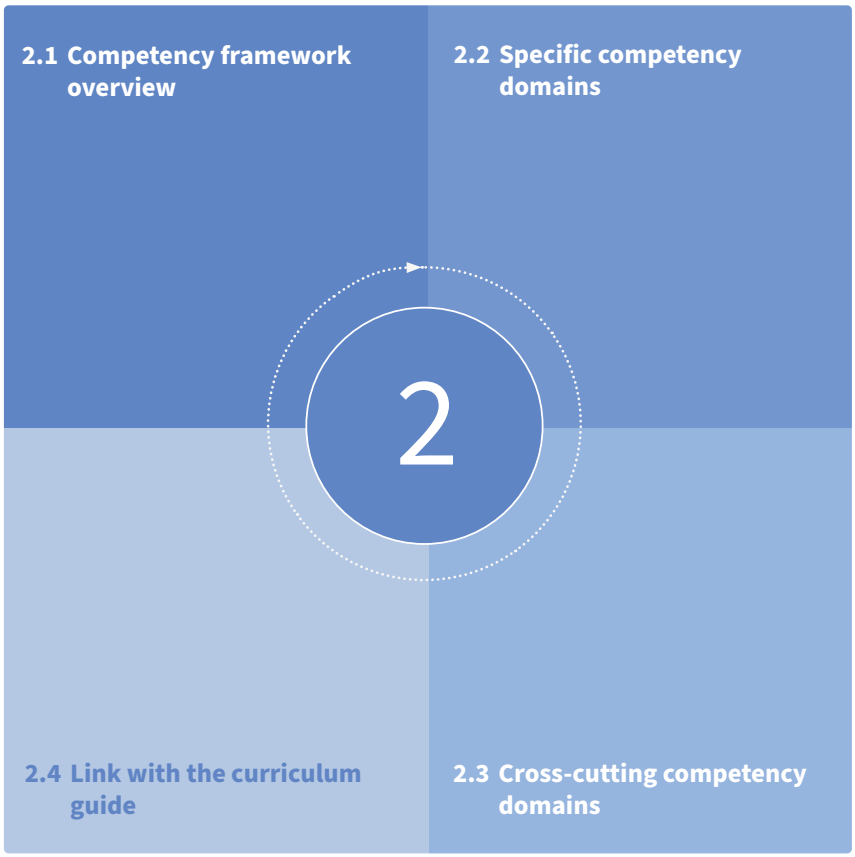
2 Competency framework

Laboratory worker conducting research.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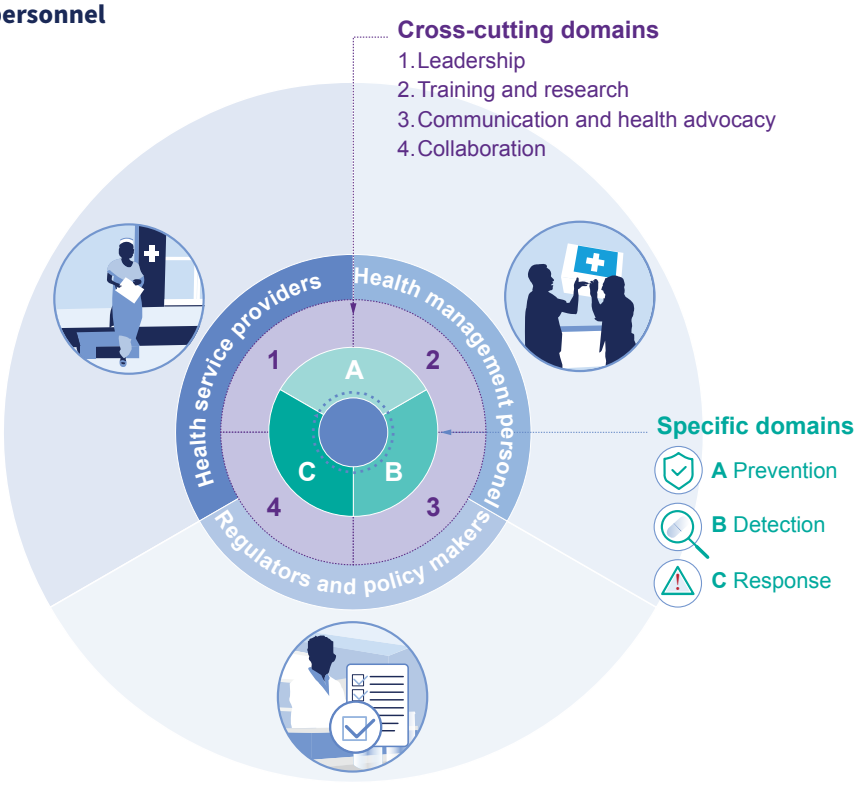
2 Competency framework

A competency framework is an inventory of the competencies required to carry out a professional activity. This trainer's toolkit includes such a framework that outlines the essential competencies required to effectively combat SFMPs at various levels of the health system. The toolkit's competency framework is aligned with two WHO competency frameworks – *Global competency framework for regulators of medicines and Global competency framework for universal health coverage* – enhancing the overall capacity to tackle SFMPs effectively *(3, 7).* This framework is an initial step in developing a competency-based education approach to SFMPs. In the competency-based approach – or outcome-based education – the competencies targeted by the training programme dictate its design, implementation approach and assessment method. This approach ensures that the educational process is aligned with the desired outcomes, focusing on the development of specific skills and knowledge that learners must demonstrate by the end of training and/or carry out in their professional activities.

2.1 Competency framework overview

The competency framework on SFMPs is organized into three thematic competency domains (prevent, detect and respond), in alignment with WHO's PDR strategy, and across four cross-cutting domains: training and research; communication and health advocacy; collaboration; and leadership (Fig. 2). Within each domain, key competencies are outlined (e.g. securing procurement to avoid SFMPs) and translated into observable enabling competencies (e.g. demonstrate appropriate demand forecasting and quantification skills to anticipate future needs and adjust inventory levels accordingly) (Table 1). The competencies are also tailored to health personnel at three levels: health service providers, health management personnel, and regulators and policy-makers (see section 1.3 for details on target audiences). It is important to note that the competency framework on SFMPs does not set a specific scope of practice. Instead, the framework should be contextualized and applied in line with the roles and responsibilities of health personnel, as defined by their professional authorities, in accordance with local regulations and practice standards.

Fig. 2. Specific and cross-cutting competency domains required to combat SFMPs for the three levels of health personnel



SFMP: substandard and falsified medical product.

Table 1. Competency framework overview

	Domains	Key competencies
Specific domains	**Prevention** 	• Securing the production of medical products to prevent the entry of SFMPs • Securing the procurement of medical products to prevent the entry of SFMPs • Securing the distribution process to prevent the entry of SFMPs • Securing the prescription, dispensing/supply and use of medical products
	Detection 	• Applying appropriate measures for detection of SFMPs throughout supply chains • Reporting any suspected case of an SFMP using appropriate reporting channels
	Response 	• Assessing risks associated with a reported case of an SFMP • Mitigating the risks associated with a reported case of an SFMP
Cross-cutting domains	**Communication** 	• Communicating effectively with stakeholders • Raising public awareness of SFMPs • Managing crisis communication about a suspected or confirmed case of an SFMP
	Collaboration 	• Collaborating with multiple stakeholders at local, regional, national or global levels
	Leadership 	• Making timely decisions with a focus on appropriateness and effectiveness • Showing creative leadership through flexible and adaptable strategies to prevent, detect and respond to SFMPs
	Education, training and research 	• Supporting and participating in research on SFMPs • Taking part in training and education activities on SFMPs

SFMP: substandard and falsified medical product.

2.2 Specific competency domains

2.2.1 Prevent

Tables 2 to 5 show the key prevention competencies for the three levels of health-related personnel who may encounter medical products and SFMPs.

Table 2. Securing the production of medical products to prevent the entry of SFMPs

Enabling competencies		
 **Level 1 (health service providers)**	 **Level 2 (health management personnel)**	 **Level 3 (regulators and policy-makers)**
Implements organizational rules, policies and procedures to ensure and validate manufacturers adhere to GMP. Ensures medical products prepared in pharmacies (e.g. extemporaneous, cytotoxic medicines) are prepared in accordance with good practices and requirements of preparation, such as calculations, appropriate formulation, procedures, raw materials and equipment. Maintains accurate and comprehensive records to meet regulatory requirements and enable traceability.	Develops and implements a robust quality management system. Exhibits leadership, management and governance in handling issues related to substandard medical products. Demonstrates appropriate skills in risk analysis, quantification and mitigation to anticipate any possibility of substandard medical products being manufactured and placed on the market. Conducts regular audits to detect any trends in deviations of manufacturing processes. Implements a system for documentation and record-keeping.	Assists manufacturers in ensuring compliance with current GMP requirements and applicable standards. Establishes and implements a robust process for issuing manufacturing licences and GMP certificates for medical products in the country in line with international standards. Monitors production processes and ensures they meet all regulatory standards, including GMP requirements. Strengthens the resources and inspection skills of the national regulatory authority for medical products. Ensures that manufacturer's control laboratory operates independently of production and guarantees the existence of validated control methods that comply with references for all batches of products manufactured.

GMP: good manufacturing practices; SFMP: substandard and falsified medical product.

Table 3. Securing procurement of medical products to the prevent entry of SFMPs

Enabling competencies		
 **Level 1 (health service providers)**	 **Level 2 (health management personnel)**	 **Level 3 (regulators and policy-makers)**
Adheres to and follows organizational rules, policies and procedures on good practices for receiving medical products from a supplier. Ensures traceability of all medical products. Ensures that donations of medical products comply with national donations policy on medicines and/or WHO guidelines for medicines donation, particularly in emergency situations.	Develops and implements robust and flexible forecasting and supply planning, including pooled procurement. Demonstrates appropriate demand forecasting and supply planning skills to anticipate future needs and adjust inventory levels accordingly. Demonstrates skills to determine technical and commercial specifications and establishes contracting with suppliers found to meet specifications. Evaluates and selects reliable suppliers based on criteria, where appropriate, including quality standards, reliability and track record, among others. Reviews certificates of compliance (e.g. good manufacturing practice certificate and WHO prequalification) from regulatory oversight bodies and prompts an audit of suppliers, as needed. Implements and optimizes data collection and supply-chain management systems to enable comprehensive product traceability. Develops and implements written procedures based on good procurement practices and national guidelines including: • appropriate forecasting and supply planning to avoid shortages and emergency orders that can lead patients to unregulated and informal markets, • selection of suppliers based on quality criteria, • regular audits of the suppliers, • quality control at delivery/ receipt of medical products (note: this is distinct from testing aspects of quality control), and • traceability of all medical products.	Develops and implements national procurement guidelines for medical products to help establishments and buyers avoid the purchase of SFMPs. Ensures implementation of all quality assurance guidelines for supply-chain integrity. Promotes processes that ensure marketing authorization is granted for medical products in the country. Ensures a rigorous process for delivering licensing to any pharmaceutical and clinical establishment involved in the supply chain of medical products (e.g. importers, wholesalers, distributers, and hospitals and pharmacies). Implements or adopts a licensing and/or accreditation programme for online retailers. Develops a national policy on donation of medical products and adopts national donation guidelines.

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

Table 4. Securing the distribution process (including transport, storage and stock management) to prevent the entry of SFMPs

Enabling competencies		
Level 1 (health service providers)	**Level 2 (health management personnel)**	**Level 3 (regulators and policy-makers)**
Adheres to and follows organizational guidelines, policies and procedures on GSDP, namely: orderly storage, good conditions, secure storage and distribution, clean storage at the specified environmental conditions, and appropriate inventory monitoring. Manages inventory levels effectively to prevent stock-outs or overstock situations to ensure continuous availability of medical products.	Implements inventory management tools and systems to monitor stock levels in real time and prevent stock-outs. Develops and implements procedures based on GSDP and national regulations to minimize the risks of SFMPs including: • storage conditions, including monitoring environmental conditions and standard warehouses, • stock security, • stock control and inventory management, and • secure and appropriate transport. Advocates for adequate funding to strengthen GSDP. Ensures that distributors/ dispensers of medical products are fully authorized.	Implements regulations, procedures and guidelines for the distribution and sale of medical products for physical establishments and online retailers. Enforces regulatory compliance through sanctions, penalties and legal action against entities that are found to be distributing SFMPs. Implements public communication actions on sanctioned establishments. Demonstrates proficiency in conducting inspections and audits of all supply-chain actors (including suppliers, manufacturers, distributors and health facilities) to verify compliance with regulatory requirements. Guarantees, through inspections, a rigorous procedure for issuing certificates of GSDP for medical products in the country, where appropriate.

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

Table 5. Securing prescription, dispensing/supply and use of medical products

Enabling competencies		
Level 1 (health service providers)	**Level 2 (health management personnel)**	**Level 3 (regulators and policy-makers)**
Complies with good practices when prescribing, dispensing, storing, distributing and/or administering medical products.	Develops and implements procedures based on national regulations and good practices for prescribing, dispensing, storing, distributing and/or administering medical products to minimize risks of SFMPs.	Enforces guidelines and standards to regulate prescribing, dispensing, storing, distributing and administering medical products.

SFMP: substandard and falsified medical product.

2.2.2 Detect

Tables 6 and 7 show the key detection competencies for the three levels of health-related personnel who may encounter medical products and SFMPs.

Table 6. Applying appropriate measures for detection of SFMPs throughout supply chains

Enabling competencies		
 **Level 1** (health service providers)	 **Level 2** (health management personnel)	 **Level 3** (regulators and policy-makers)
Demonstrates commitment to following procedures and guidelines for detecting and reporting SFMPs according to the roles and responsibilities of personnel at this level. Monitors appropriately storage conditions of medical products (e.g. temperature, humidity and light). Demonstrates good observational skills to visually inspect medical products for signs that they may be substandard or falsified.	Demonstrates up-to-date scientific expertise to understand the methods used to test falsified medical products, apply them correctly and interpret the results properly. Ensures suitable quality control tests are performed and managed appropriately. Plans and develops procedures for risk-based (post) market surveillance. Ensures the quality, accuracy and reliability of testing procedures and results through quality assurance processes and adherence to internationally recognized standards. Uses handheld devices to screen for SFMPs.	Applies guidelines and procedures that control the production, distribution and dispensing of medical products to ensure their quality through regulatory oversight, including (post) market surveillance, in line with national legislation and regulations on medical products Applies mechanisms to detect and remove falsified medical products circulating in local markets/ jurisdictions. Applies a risk-based strategy to conduct post-market surveillance for SFMPs in line with national legislations and regulation of medical products within regulated and unregulated supply chains, including online and informal markets. Identifies and collaborates with referral institutions and laboratories that demonstrate proficiency and experience in analytical techniques and technologies used for the detection and analysis of medical products, such as spectroscopy, chromatography and mass spectrometry. Implements traceability systems that can help track and verify medical products throughout the supply chain, detect irregularities and prevent the entry of SFMPs. Strengthens other regulatory functions that will indirectly affect entry of SFMPs.

SFMP: substandard and falsified medical product.

Table 7. Reporting suspected cases of SFMPs using appropriate reporting channels

Enabling competencies		
 **Level 1** (health service providers)	 **Level 2** (health management personnel)	 **Level 3** (regulators and policy-makers)
Accurately reports suspected cases of SFMPs to the appropriate authorities (local or national) and, where appropriate, to suppliers or manufacturers. Monitors and reports adverse reactions, medication errors and other safety concerns related to medical products to national regulatory authorities, pharmacovigilance centres and manufacturers (pharmacovigilance). Equips patients with resources to report any suspected adverse events or problems with medication.	Promotes a reporting culture and implements procedures to adequately report any suspected case to the relevant local or national authority. Enhances coordination mechanisms between service providers and pharmacovigilance centres to report all the suspected adverse reactions to detect any possible SFMPs.	Proportionately, consistently and transparently enforces compliance with national regulation on medical products. Enforces a legal framework for the reporting of any suspected case of SFMPs. Implements and maintains user-friendly tools to facilitate reporting suspected SFMPs, including for the general public. Promotes and supports a national pharmacovigilance programme. Promotes triangulation of data and sharing of information across incident reporting systems (e.g. pharmacovigilance, post-market surveillance, SFMP databases and international health regulations). Analyses incidents of suspected SFMPs and makes clear and comprehensive requests for analysis to manufacturers and quality control laboratories to confirm reported suspected cases. Reports confirmed cases of SFMPs to the WHO's global surveillance and monitoring system for SFMPs.

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

2.2.3 Respond

Tables 8 and 9 show the key response competencies for the three levels of health-related personnel who may encounter medical products and SFMPs.

Table 8. Assessing risks associated with a reported case of an SFMP

Enabling competencies		
Level 1 (health service providers)	**Level 2 (health management personnel)**	**Level 3 (regulators and policy-makers)**
Collates, reviews, maintains and updates relevant information related to suspected cases of SFMPs and patient data. Participates actively in the risk assessment process.	Gathers relevant data and produces credible information from reliable sources on supply chain security and quality of medical products in circulation. Identifies and assesses possible structures and beneficiaries that increase the risk of SFMPs. Documents, and where relevant, conducts appropriate investigations on the origin and enabling factors of suspected SFMPs. Collaborates with regulatory authorities for further investigations and assessment of public health risk.	Assesses the reliability of sources and credibility of information, and evaluates the need for additional data to document suspected cases of SFMPs. Identifies and assesses the risk to the population in implementing an immediate public health response. Collects an appropriate number of samples and organizes additional analyses to confirm status beyond reasonable doubt.

SFMP: substandard and falsified medical product.

© WHO / Khalil Ashawi

Hospital pharmacy storage shelf with temperature tracker.

© WHO / Daniel Paluku Kahandukya

Using computers to quickly access laboratory results.

Table 9. Mitigating the risks associated with a reported case of an SFMP

Enabling competencies		
Level 1 (health service providers)	**Level 2 (health management personnel)**	**Level 3 (regulators and policy-makers)**
Ensures the effective management of cases of exposure to SFMPs according to treatment guidelines. Takes rapid action to remove the immediate risks (e.g. quarantine of the suspected products). Follows instructions for recall of products as requested by supplier and/or national authority, including notification of patients when necessary. Applies legislation and procedures relevant to waste management of SFMPs.	Demonstrates critical inquiry and scientific/evidence-based method in managing patients exposed to SFMPs or other situations in which SFMPs are involved. Organizes recall of the medical products in the structure and verifies the availability of quality-assured replacement products. Identifies and implements short-term and long-term actions to reduce the risks associated with reported cases of SFMPs with the aim of preventing recurrence. Develops guidance for patients and health care professionals following the consumption of a suspected SFMP.	Links to any relevant stakeholders and teams within the regulatory authorities tasked with handling incidents and complaints. Develops effective strategies to protect public health and prevent recurrence of incidents of SFMPs (e.g. root cause analysis, and corrective and preventive actions). Organizes recalls of SFMPs with support of supplier, including dissemination of national alerts. Engages in partnerships such as with law enforcement and customs authorities to respond effectively and provide evidence for any criminal case proceedings. Takes appropriate legal action against perpetrators and ensures a transparent and timely legal process. Ensures that waste management legislation covers SFMPs.

SFMP: substandard and falsified medical product.

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Person holding a medicine tablet.

© WHO / Yoshi Shimizu

Medicines in a pharmacy at a social clinic.

2.3 Cross-cutting competency domains

2.3.1 Communication and health advocacy

Tables 10, 11 and 12 show the key communication and health advocacy competencies for the three levels of health-related personnel who may encounter medical products and SFMPs.

Table 10. Communicating effectively with stakeholders

Enabling competencies		
Level 1 (health service providers)	**Level 2 (health management personnel)**	**Level 3 (regulators and policy-makers)**
Demonstrates good communication skills, including: • using audience-appropriate language, • showing empathy and respect for patients, • encouraging open and non-judgemental communication between patients and health care providers on concerns or suspicions in quality of medical products and fostering a collaborative approach to ensure patient safety, and • using culturally appropriate non-verbal communication. Prepares general documentation in appropriate format and language, suitable for target audiences.	Communicates clearly and quickly with suppliers, and internal and external stakeholders to solve problems and anticipate challenges. Drafts technical documents, such as guidelines, procedures and technical reports, in line with best practices.	Effectively communicates regulatory requirements, risks and compliance expectations to stakeholders, including health care professionals, suppliers and the public, to raise awareness and promote adherence to quality standards. Ensures transparency in regulatory decisions by making them accessible to others.

© WHO

Regional training session.

© WHO

Training in a hospital.

Table 11. Raising public awareness of SFMPs

Enabling competencies		
Level 1 (health service providers)	**Level 2** (health management personnel)	**Level 3** (regulators and policy-makers)
Supports and participates in initiatives that raise public awareness about the dangers of SFMPs to empower patients to make informed decisions about their health care.	Identifies audience's underlying needs and motivations, as well as their interests and issues, when formulating a communication strategy, by involving health service providers and patients.	Analyses and interprets data on quality, distribution and adverse events of medical products to identify trends and patterns. Plans, develops and measures the success of effective educational and awareness campaigns for diverse audiences and contexts. Adapts content, style and medium of communication to the context and diverse audiences. Implements and informs on an online accreditation, licensing programme and/or website directing the public to safe online retailers. Increases political awareness and advocates at the highest levels for the need to support and dedicate resources to prevent, detect and respond to SFMPs.

SFMP: substandard and falsified medical product.

Table 12. Managing crisis communication about a suspected or confirmed case of an SFMP

Enabling competencies		
Level 1 (health service providers)	**Level 2** (health management personnel)	**Level 3** (regulators and policy-makers)
Discusses with communities and health providers the appropriate guidance after the consumption of a suspected SFMP. Interprets and addresses questions effectively. Responds appropriately by delivering information and evidence in a clear and coherent manner.	Organizes appropriate response for the working environment and implements the measures requested by the authorities.	Prepares a crisis communication plan including pre-identification of appropriate channels and content. Communicates complex issues clearly and credibly to diverse audiences (government, procurement agencies, wholesalers and importers, health and care workers and the public). Provides appropriate messages on the measures to be taken at the different levels of the health care system. Handles difficult on-the-spot questions (e.g. from public officials, senior executives, interest groups, communities and the media).

SFMP: substandard and falsified medical product.

2.3.2 Collaboration

Table 13 shows the key collaboration competencies for the three levels of health-related personnel who may encounter medical products and SFMPs.

Table 13. Collaborating with multiple stakeholders at local, regional, national or global levels

Enabling competencies		
 **Level 1 (health service providers)**	 **Level 2 (health management personnel)**	 **Level 3 (regulators and policy-makers)**
Works effectively within an interprofessional environment. Fosters collaboration with health care teams, regulatory authorities and other stakeholders to share information, coordinate efforts and implement strategies to combat SFMPs and enhance patient safety.	Fosters collaboration with teams, regulatory authorities and other stakeholders to share information, coordinate efforts and implement strategies to combat SFMPs and enhance patient safety. Works effectively within relevant local, regional and national authorities.	Facilitates transparent and coordinated consultation, cooperation and collaboration, from a public health perspective, with relevant stakeholders both regionally and globally (e.g. government, international organizations, the private and non-profit sectors, and civil society). Exchanges experiences, lessons learnt, best practices and information on ongoing activities at national, regional and global levels. Ensures close coordination with all supply-chain actors and with authorities, customs, law enforcement agencies, ministry of justice (prosecutors and magistrates) and other health authorities to strengthen regulatory frameworks and enforcement mechanisms.

SFMP: substandard and falsified medical product.

2.3.3 Leadership

Tables 14 and 15 show the key leadership competencies for the three levels of health-related personnel who may encounter medical products and SFMPs.

Table 14. Making timely decisions with a focus on appropriateness and effectiveness

Enabling competencies		
 **Level 1** (health service providers)	 **Level 2** (health management personnel)	 **Level 3** (regulators and policy-makers)
Demonstrates clinical judgement, recognizes affected patients and escalates management appropriately. Commits to continuous improvement through regular monitoring, evaluation and optimization of processes for using medical products and patient safety initiatives.	Demonstrates a good understanding of, and complies with, national and international regulatory frameworks governing medical products. Takes informed decisions and implements policies and procedures based on available evidence, expert insights and ethical considerations to safeguard patient safety and public health.	Promotes and enforces national and international regulatory frameworks governing medical products through adequate legal provisions and regulations. Maintains a national action plan to prevent, detect and respond to SFMPs. Uses evidence, expert insights and ethical considerations to guide decision-making and policy development.

SFMP: substandard and falsified medical product.

Table 15. Showing creative leadership through flexible and adaptable strategies to prevent, detect and respond to SFMP

Enabling competencies		
 **Level 1** (health service providers)	 **Level 2** (health management personnel)	 **Level 3** (regulators and policy-makers)
Adheres to ethical principles, transparency and integrity in prescribing, dispensing, supplying and administering medical products as well as medication management activities to build trust and confidence in patients and health providers.	Actively contributes to the design and implementation of a quality assurance system that promotes the prevention and detection of and response to SFMPs. Organizes regular internal audits to ensure that good practices and site procedures safeguarding the prevention and detection of and response to SFMPs are respected. Performs risk assessment to assess potential vulnerabilities in the supply chain and implement risk mitigation strategies. Adapts quickly to unforeseen changes in demand, market conditions or operational constraints in the supply chain. Maintains an active interest in medical products, and their supply and management within teams.	Demonstrates necessary inventive and critical thought in managing exposure and response to SFMPs, including continuous improvement of the current WHO's prevent–detect–respond strategy.

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

2.3.4 Research, training and education

Tables 16 and 17 show the key research, training and education competencies for the three levels of health-care-related personnel who may encounter medical products and SFMPs.

Table 16. Supporting and participating in research on SFMPs

Enabling competencies		
Level 1 (health service providers)	**Level 2 (health management personnel)**	**Level 3 (regulators and policy-makers)**
Actively participates in research activities through, e.g. data collection and reporting.	Identifies and articulates research questions and designs research protocols related to SFMPs that address gaps in data and current knowledge.	Advocates for the necessity of data collection and research to generate broader evidence and promote evidence-based decisions, policies and procedures.

SFMP: substandard and falsified medical product.

Table 17. Taking part in training and education activities on SFMPs

Enabling competencies		
Level 1 (health service providers)	**Level 2 (health management personnel)**	**Level 3 (regulators and policy-makers)**
Delivers interactive presentations/ trainings and moderates discussions on SFMPs. Educates the community on SFMPs and the potential health risks associated with their use, including ineffective treatment or prevention, adverse reactions, serious deterioration in health conditions and death. Advises patients on preventives measures for SFMPs, including: • List of authorized retailers to obtain medical products to reduce exposure to SFMPs, including pharmacies and health facilities • Give example of suspicious signs of unauthorized sources (informal market selling medical products, suspiciously low-priced medical products and sources that sell prescription only medicines without a prescription)	Designs and develops educational programmes and courses focused on preventing, detecting and responding to SFMPs tailored to different target audiences, such as undergraduate and postgraduate learners, health and care workers, public health officers, communities and the public. Delivers effective and engaging educational sessions on SFMPs, adapting teaching methods (e.g. lectures, workshops, case studies, role-play, simulation exercise and online learning) to meet the needs of different learners and promotes active participation and learning. Informs and educates health and care workers on the policy and procedures in place in the working environment to ensure the integrity of the medical product supply chain. Commits to staying updated on the latest developments, research findings and best practices in the field of SFMPs to enhance educational content and delivery.	Advocates for integration of SFMPs in university curricula for health providers. Plans and implements periodic training courses for the staff of national regulatory authorities involved in the inspection of medical products. Organizes dedicated training for national stakeholders.

Table 17. Taking part in training and education activities on SFMPs *(continued)*

Enabling competencies		
Level 1 (health service providers)	**Level 2** (health management personnel)	**Level 3** (regulators and policy-makers)
Empowers patients on suspicious signs of SFMPs emphasizing changes in packaging, appearance, expiry date. Commits to ongoing training and capacity-building initiatives for staff members to enhance their awareness and understanding of SFMP risks and regulatory requirements.		

SFMP: substandard and falsified medical product.

2.4 Link with the curriculum guide

The specific and cross-cutting competency domains outlined in this section correspond with the curriculum guide of the trainer's toolkit. Each of the three modules of the curriculum guide – prevent, detect, respond – will have corresponding competencies that refer to the knowledge, skills and attitudes required for each level, which are developed through education, training and experience. Consistent with the *WHO Global competency framework for regulators of medicines (3)*, the following descriptions apply to competencies used in this document:

- Knowledge: awareness, information and/or understanding the facts, rules, principles, guidelines, concepts, theories or processes needed to successfully perform a task. This is acquired through learning and experience.
- Skills: capacity to perform mental or physical tasks with a specified outcome.
- Attitudes: personal characteristics (e.g. work habit, emotion and way of interacting with others) that contribute to effective work performance.

Training of nurses.