1 Introduction

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Laboratory worker inspecting tablets.


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1 Introduction

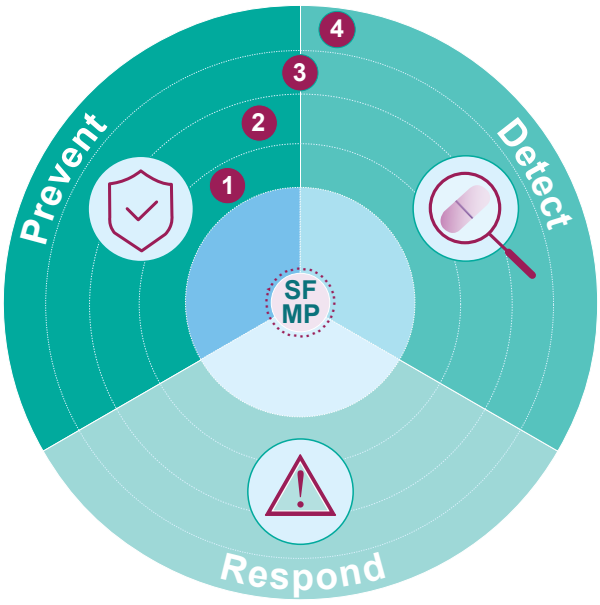
1.1 Importance of standardized training for SFMPs

Substandard and falsified medical products (SFMPs) are an unacceptable and preventable threat to both individual and public health. The World Health Organization (WHO) and its Member States have developed a holistic prevent–detect–respond (PDR) strategy to tackle SFMPs (Fig. 1) as well as a complementary reporting system in the Global Surveillance and Monitoring System (GSMS) *(1, 2)*.

One of the core strategic pillars of the WHO PDR strategy is promoting education, awareness and active involvement of health care and other personnel who are engaged with medical products and communities. In addition to physicians, pharmacists and nurses, this can include workers in health and pharmaceutical systems such as regulators for health products, supply-chain personnel, customs and law enforcement personnel and pharmacovigilance officers, among others.

There is a clear need for comprehensive and multidisciplinary training on SFMPs globally. While local, regional and professional training may exist, no internationally standardized and/or harmonized training is available for health and care workers who are dedicated to SFMPs. Similarly, no standardized training is available for health and care workers in health facilities or centres, the medical product industry or staff from international organizations and nongovernmental organizations (NGOs) working in the health sector.

Fig. 1. Strategic pillars of WHO's prevent–detect–respond strategy



SFMP medical products

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

Detect
1. Border control
2. Reporting system
3. Risk-based inspection and surveillance
4. Access to laboratories and screening technologies

Respond
1. Alerts and recalls
2. Regulatory strenghtening
3. Transparent legal process
4. Evidence-based policy and procedure

SFMP: substandard and falsified medical products; WHO: World Health Organization.
Source: WHO; 2017 *(1)*.

1.2 Purpose and scope of the trainer's toolkit

This trainer's toolkit is designed to support the education and training of learners and professionals from various educational backgrounds working in the health system, with the aim of harmonizing workforce development initiatives to effectively address the challenges of SFMPs. Aligned with the WHO PDR strategy, the trainer's toolkit provides a comprehensive competency framework, a curriculum guide, and technical resources and guidance material to empower trainers to effectively plan, develop and deliver SFMP training programmes. The technical content detailed in the modules is not intended to be exhaustive. Instead, the trainer's toolkit aims to provide modular resources that can be adopted and adapted based on the competency level of the learner.

This toolkit is specifically designed for trainers who are already familiar with the topic of SFMPs. It is not a resource meant to be used "off the shelf"; instead, it requires thoughtful adaptation to fit the context and competency level of the learners. The toolkit is organized across various chapters (modules), allowing trainers to explore more deeply various topics related to SFMPs.

1.3 Target audience of the trainer's toolkit

This trainer's toolkit is targeted at academic teachers (undergraduate and postgraduate levels), instructors for continuing professional education and trainers for in-service training (which can include international organizations, regulatory professionals and civil society, among others). It aims to equip such professionals with the necessary tools, knowledge and skills to deliver effective training on SFMPs. The trainer should adapt the toolkit to the specific roles that those participating in the training play in the health system, especially when professionals have multiple roles (e.g. prescription and procurement). Effective communication between all actors within the system is crucial for the successful implementation of strategies to combat SFMPs. Likewise, coordination and information-sharing across sectors is essential to ensure the fight against SFMPs is comprehensive and effective.

The trainer's toolkit therefore aims to support the implementation of training programmes based on a competency-based approach (knowledge, skills and attitudes) for a large and diverse range of learners, organized across three levels of health care personnel.

1.3.1 Level 1: health service providers

Their work involves direct contact with patients and communities in both public and private health sectors. These health workers require an adequate level of knowledge, skills and attitudes to be able to promptly identify an SFMP and take individual action within their immediate professional environment.

These professions include prescribers, dispensers, nurses, community health workers, and other professions in the health system and/or social service sectors who may need to be aware of the risks of SFMPs but have no direct responsibility in the procurement and supply management of medical products.

1.3.2 Level 2: health management personnel

Their work involves activities related to the procurement and management of medical products, carried out in public or private clinical or pharmaceutical establishments, such as pharmacies, wholesalers and distributors. Health management personnel should be able to explain the nature and causes of SFMPs, and the main means of prevention, detection and response to them.

These professions include health and non-health professionals with direct responsibility for procurement and supply management of medical products at any level of the health system, including supervision roles. They include procurement officers, chief pharmacists or other professionals managing the pharmacies of health care facilities, logisticians working in pharmaceutical depots, supervisors of supply-chain management activities, and staff at NGOs responsible for the procurement and distribution of medical products.

1.3.3 Level 3: regulators and policy-makers

Their work is primarily related to public administration, but can also include personnel involved in teaching, research, and development and implementation of appropriate resources, policies and decisions to combat SFMPs.

These professions include health and non-health workers in technical positions as well as policy decision-makers within institutions, such as national and regional regulatory authorities (NRRAs), quality control laboratories, ministries, development programmes, international organizations, public health institutes and law enforcement. They include lecturers and researchers involved in teaching and research about SFMPs.

It is important to note that levels in the trainer's toolkit refer to the different structures within the health system, ranging from point-of-care professionals to high-level policy-makers. These levels do not imply a hierarchical structure but rather recognize that different roles within the system require distinct sets of skills and knowledge. This is in contrast to related competency frameworks, such as the *Global competency framework for regulators of medicines (3)*, where levels express proficiencies (i.e. foundational, intermediate and advanced).

1.4 How to use the trainer's toolkit

The toolkit aims to support educators in planning, developing and delivering a training programme on SFMPs, depending on context, audience and available resources. The success of the training programme depends on the extent to which it responds to the needs of the learners. This toolkit is intended to guide the development of training resources to ensure there are opportunities for group interaction, allowing both learners and educators to take part in the training and learn from one another.

1.4.1 Available tools in the toolkit

The trainer's toolkit is a handbook to support trainers who design and deliver curricula on SFMPs. It includes the following parts.

- **Competency framework**. This outlines a set of specific cross-cutting competencies required to tackle the issue of SFMPs. It serves as a basis for curriculum development to ensure consistency in training for learners and professionals to meet the challenges of SFMPs.
- **Curriculum guide**. This is organized into four modules: an introductory module on SFMPs (module A) and three modules aligned with the WHO PDR strategy (modules B, C and D). Each module includes an overview, teaching recommendations and defined learning objectives that outline the required knowledge, skills and attitudes. The curriculum guide is to be used as training material on the issue of SFMPs, as each module offers comprehensive content that training programmes should address for various competency-based audiences.
- **Trainer's guide**. This has step-by-step instructions for successfully implementing and delivering training programmes on SFMPs.
- **Technical resources and reference documents**. These are additional reading materials and sources of evidence to support the concepts covered in the curriculum guide. Resources may include WHO publications, guidelines, scientific papers, manuals, or other material relevant to SFMPs.

1.4.2 Adopt and adapt principle

This trainer's toolkit is not intended to be a stand-alone training product or to provide ready-to-use course content. Instead, its comprehensive set of materials should be considered a flexible resource based on the adopt and adapt principle for developing learning resources *(4)* . Section 3 of the toolkit includes a trainer's guide that provides guidance to trainers on how to develop, implement and evaluate effective training on SFMPs.

In developing and implementing an SFMP training programme, adopt means trainers can identify, curate and select from the range of available resources only the parts that are relevant and applicable to their specific contexts and training objectives. Adapt, meanwhile, means trainers can and are encouraged to modify material with consideration of the local environment, available resources, needs, requirements, characteristics and experience of learners. While promoting foundational content to be retained, the intention of adaptation is to promote flexibility and stimulate ownership of locally contextualized content, methods and strategies to close the gaps and meet particular needs of learners.

1.5 How the trainer's toolkit was developed

To enhance awareness, knowledge and skills, a standardized, comprehensive and multidisciplinary undergraduate university training programme for pharmacists focusing on SFMPs was collaboratively developed by WHO and the International Pharmaceutical Federation (FIP) in 2021 *(5)*. This pilot programme was implemented in four sub-Saharan African countries. An evaluation in 2023 yielded recommendations for enhancing the content of the programme. It was also considered that the target audience needed to be expanded beyond undergraduate pharmacy students to include health and care workers at various levels of health systems and other relevant areas *(6)*.

This trainer's toolkit builds on the pilot training programme. The technical and operational aspects of the toolkit were developed by WHO, a consortium of five academic institutions (EHESP-International Rennes, France; Institute of Tropical Medicine, Antwerp, Belgium; Geneva University Hospitals, Geneva, Switzerland; University of Douala, Douala, Cameroon; and Cheikh Anta Diop University Dakar, Dakar, Senegal) and a consultant. An initial round of expert consultations mapped the elements to be updated (October to November 2023), while WHO technical teams collated the tools within the toolkit.

Operational aspects were considered to maximize the usefulness and use of the toolkit. A benchmarking exercise against existing training programmes was supplemented by a comparative toolkit analysis. Discussions on the scope of the curriculum guide and competency framework demonstrated the need for additional resources, such as sample decks as well as supplementary exercises and case studies that will need to be developed separately. Consultations with the WHO Academy and other experts also helped accelerate the development of a website. Between June and August 2023, a draft of the toolkit was made available on the Ideagen PleaseReview platform for public consultation. A systematic approach was applied to review and incorporate the feedback from the public consultations through an informal technical advisory group (September to October 2023).

Medicines in blister packs.

Temperature control at storage.