# Curriculum for pharmacy students on substandard and falsified medicines

## Curriculum guide and competency framework

2021

FIP Development Goals

International Pharmaceutical Federation

# Colophon



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# Forewords

**By Pernette Bourdillon-Esteve, Team lead (a.i.) Incidents and substandard/falsified medical products, World Health Organization (WHO)**

The WHO's mission to promote health, keep the world safe and serve the vulnerable aims for one billion more people to benefit from universal health coverage, to be better protected from health emergencies, and to enjoy better health. Substandard and falsified (SF) medical products squander public health investments because they harm patients, undermine trust in health systems, waste resources, contribute to antimicrobial resistance, and ultimately obstruct access to safe, effective and quality medical products. SF medical products are a constant, pervasive and unacceptable public health threat.

In 2017, the WHO estimated that more than one in 10 medicines in low- and middle-income countries was substandard or falsified. This means that these countries spend well over USD 30 billion annually on SF products — a figure that excludes the full range of socio-economic costs to individuals and societies. SF products are often difficult to detect, even for trained professionals. While failing to treat patients (often with serious consequences), they may not cause obvious adverse reactions. Even when detected, they are often under-reported, which would otherwise prevent wider harm.

The WHO's holistic strategy of prevention, detection and response to SF medical products requires full inclusion of pharmacists, pivotal public heath actors at the interaction between patients and medical products. As guardians of the supply chain's integrity, pharmacists' unique position allows them to safeguard the quality and safety of medical products before distribution. Their vigilance is indispensable to prevent, detect and respond to SF medical products. However, too few pharmacists receive formal training on this issue during or after education.

This pilot project addresses the training gap and advances the essential role of pharmacists. Funded by the European Commission, it could not have been realised without the drive and support of the International Pharmaceutical Federation (FIP), the Commonwealth Pharmacists' Association and the Order of Francophone Pharmacists, as well as the experts' contributions coordinated by FIP. The WHO is grateful to the five participating universities: Cameroon's University of Douala, Nigeria's' University of Benin, Senegal's Université Cheikh Anta Diop, Tanzania's Muhimbili University, and Uganda's Makerere University College.

It is hoped that this project will be a steppingstone towards greater awareness on how to prevent, detect and respond to SF medical products, both within pharmacists' communities and beyond.

## By Dominique Jordan, president, and Catherine Duggan, CEO, International Pharmaceutical Federation

As FIP president and CEO, we are seriously concerned about the continuing, even increasing, risk to public health represented by substandard and falsified (SF) medical products, particularly in countries where legislation governing the manufacture and distribution of medicines, or the enforcement of legislation, is ineffective. In sub-Saharan Africa, for example, the need for action is great. The massive circulation of poor quality, harmful and counterfeit active ingredients and finished products in international commerce can seriously reduce the quality of patient care and increase the risk to harm people.

Falsification and poor quality completely undermine the long-established controls of quality, safety and efficacy of medical products that are designed to protect the public. The key to the reduction in the availability of SF medical products is the maintenance of the integrity of the quality controls at all stages in the manufacturing and distribution channel for medicines.

FIP has been speaking out against SF medicines for over 20 years. The commitment of the profession has been visible through our Statement of Policy on Counterfeit Medicines (since 2003) and through various initiatives and projects we have been working on in the past decades — both internally and with our partners from healthcare professional bodies, industry partners, and NGOs.

We believe that pharmacists, pharmaceutical scientists and educators can be a vital asset in assuring the safety of patients through their active participation in the fight against these products. As the final member of the pharmaceutical distribution chain as well as often being supply chain managers, pharmacists are key in combating SF medical products. In community and hospital settings, pharmacists can quickly detect SF medical products that have penetrated the supply chains and report them to authorities, as well as educate and advise patients who have been exposed to them. Therefore, we are honoured to have taken on this challenge to develop this specific bilingual modular educational curriculum to educate future pharmacists on SF medical products. We believe this module will not only raise awareness of the dangers of SF medicines but will also concretely outline how pharmacists can improve reporting and intervening behaviours in high-risk regions of the world, like sub-Saharan Africa.

We thank the World Health Organization for being our partner in this project and the European Commission for their financial contributions. We are also grateful for the support of leading global partners La Conférence Internationale des Ordres de Pharmaciens Francophones and the Commonwealth Pharmacists Association. In particular, the five pilot Universities in Sub-Saharan Africa were essential in development and deployment of this first-of-its-kind curriculum.

It is our wish that this curriculum, Global Competency Framework for Pharmacists' Education and Training on Substandard and Falsified (SF) Medical Products and all related tools will be useful not only for our existing collaborators, but also for more countries in the African region and beyond.

# Executive summary

Substandard and falsified (SF) medical products are a major public health threat jeopardising access to safe, quality, efficacious and affordable medical products. SF medical products can contain no or an inappropriate level of active ingredient, making them incapable of curing the disease or causing misleading therapeutic results.[1] In addition, falsified products can contain toxic substances that can lead to disability or death.[2] The consequence is a lack of confidence in healthcare.[3,4] In particular, falsification of antibiotics is expected to be a major contributor to antimicrobial drug resistance. All medicines and medical devices are in danger, both the lifesaving and lifestyle ones, generic and branded medicines, and increasingly also biologic medicines.[5,6]

The World Health Organization (WHO) is an intergovernmental agency that facilitates international health matters. It belongs to the United Nations family and is composed of 194 different member states. The WHO conducts a range of activities with member states and stakeholders to minimise the risks from SF medical products, including developing policy, identifying good practice, collecting and analysing data, and issuing alerts, to better inform decision making in investing to secure supply chains and build regulatory capacity to prevent SF medical products from reaching patients.

Although it is extremely difficult to quantify the problem precisely, recent efforts by the WHO and others to support countries in tracking and reporting SF medical products suggest the problem is on the rise.

The WHO global surveillance and monitoring system (GSMS) for SF medical products has received over 2,000 notifications of SF medical products since 2013. This figure could also be an underestimate, as healthcare professionals have been shown to report only serious incidents, according to GSMS data. Of the regions identified within the report, sub-Saharan Africa accounted for the majority of the GSMS notifications.[7] In 2017, the WHO estimated that 1 in 10 medicines in low- and middle-income countries was substandard or falsified, costing an estimated USD 30.5 billion each year.[8]

This is in part because globalisation and e-commerce have increased the complexity of the supply chain for medicines, providing numerous entry points for unethically and illegally produced medical products. Globalisation of the market in active pharmaceutical ingredients and finished medical products allows medical products to be manufactured in one part of the world, packaged in another and supplied to a third. The exponential increase in internet connectivity and mobile telecommunications has opened a global marketplace for suppliers and consumers of medical products.

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[1] World Health Organization: What Do SSFFC Medical Products Contain? Geneva: World Health Organization, 2017. Available at: http://www.who.int/medicines/regulation/ssffc/faq-ssffc_1-10/en/index2.html

[2] World Health Organization: What Is the Harm Caused by SSFFC Medical Products? Geneva: World Health Organization, 2017. Available at: http://www.who.int/medicines/regulation/ssffc/faq-ssffc_1-10/en/index5.html

[3] Newton PN, Green MD, Fernández FM, Day NP, White NJ. Counterfeit anti-infective drugs. Lancet Infect Dis. 2006;6(9):602-13.

[4] Nsimba SE. Problems associated with substandard and counterfeit drugs in developing countries: a review article on global implications of counterfeit drugs in the era of antiretroviral (ARVs) drugs in a free market economy. East Afr J Public Health. 2008;5(3):205-10.

[5] World Health Organization: Which Medical Products Are Most Affected? Geneva: World Health Organization, 2017. Available at: http://www.who.int/medicines/regulation/ssffc/faq-ssffc_1-10/en/index1.html

[6] World Health Organization: WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products. Geneva: World Health Organization, 2017. Report No.: WHO/EMP/RHT/2017.01.

[7] WHO Global Surveillance and Monitoring System for substandard and falsified medical products. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO. Available at: https://www.who.int/medicines/regulation/ssffc/publications/GSMSreport_EN.pdf?ua=1

[8] A study on the public health and socioeconomic impact of substandard and falsified medical products: World Health Organization; 2017.

Despite an increasing focus on public health and wellbeing among global leaders, many medical systems are still undermined by SF medicines. Sub-Saharan Africa has shown considerable death tolls as a result of SF medicines. One study modelling antimalarial therapies estimated that SF medicines could cause 529 additional deaths per million malaria cases annually due to inadequate treatment.[9] When combined with data from the Clinton Health Access Initiative, this suggests as many as 267,000 additional deaths per year.[6] Therefore, it is clear that reporting and intervention are required to reduce the unacceptable loss of human life.

Thoroughly understanding the global threat posed from SF medical products is important to better prevent them from reaching patients. Healthcare professionals are key in responding to them proportionately and consistently — quickly detecting SF medical products when they have penetrated supply chains and reporting them to authorities, as well as educating and advising patients who have been exposed to them.

Although an accurate and reliable source of SF reports, healthcare professionals cite a variety of barriers to reporting, including but not limited to a lack of awareness, a lack of feedback, overcomplicated reporting systems, and even fear of being reprimanded by their superiors.[7] As a result, the WHO proposed a solution with the production of a modular educational curriculum to improve reporting and intervening behaviours of frontline healthcare professionals, specifically pharmacists, in high-risk regions of the world like sub-Saharan Africa.

[9] Kaur H, Allan EL, Mamadu I, Hall Z, Ibe O, El Sherbiny M, et al. Quality of Artemisinin-Based Combination Formulations for Malaria Treatment: Prevalence and Risk Factors for Poor Quality Medicines in Public Facilities and Private Sector Drug Outlets in Enugu, Nigeria. PLOS ONE. 2015;10(5):e0125577.

# 1. Introduction

Recognising that substandard and falsified (SF) medical products are an unacceptable public health threat, the WHO and its member states have developed a holistic prevention-detection-response strategy to address the issue.[10] Within the prevention pillar, quality ought to be demanded at all levels to guarantee supply chain integrity and product quality. This requires full involvement of those healthcare professionals who work closest to medical products and patients, namely, pharmacists.

Currently, in sub-Saharan Africa, there is no standardised, formal or harmonised university training for pharmacists dedicated to SF medical products. This region, which is most vulnerable to these products, is also that in which the WHO technical unit dealing with the issue has conducted most activities in close collaboration with national regulatory authorities, making it the most logical location to pilot this project. There is a clear need for comprehensive and multidisciplinary training in SF medicines for pharmacists. Therefore, the International Pharmaceutical Federation together with the WHO developed this compulsory education component on SF medicines in four African countries as part of a pilot project.[11]

This curriculum guide is to be used as training material on the issue of SF medical products that will be incorporated into the pharmaceutical university curriculum in the African region. It is designed to increase and improve the education and awareness levels of pharmacists in order to better prevent SF medical products reaching patients.

This guide contains the Global Competency Framework for Pharmacists' Education and Training on Substandard and Falsified (SF) Medical Products based on learning objectives for attainment of knowledge, skills and attitudes and the comprehensive curriculum training materials.

This curriculum is designed to teach pharmacy students how to avoid, detect and report SF medicines, and how to advise affected patients and consumers. Pharmacy students at five pilot universities in sub-Saharan Africa were chosen as the target for the curriculum (Figure 1). These five pilot universities were chosen based on recommendations from the WHO Africa Regional Office and FIP. Ideally, the curriculum will be expanded to other schools of pharmacy and regions across the globe.

[10] A70/23 - Member State Mechanism on Substandard/Spurious/Falsely-labelled/Falsified/ Counterfeit Medical Products. Report by the Director-general. Seventieth World Health Assembly, 2017. Available at: https://www.who.int/medicines/regulation/ssffc/mechanism/A70_23-en6-14.pdf?ua=1

[11] Ferrario A, Orubu ESF, Adeyeye MC, Zaman MH, Wirtz VJ. The need for comprehensive and multidisciplinary training in substandard and falsified medicines for pharmacists. BMJ Global Health. 2019;4(4):e001681.

| University | Country | Teaching language |
|---|---|---|
| University of Douala | Cameroon | French |
| University of Benin | Nigeria | English |
| Université Cheikh Anta Diop | Senegal | French |
| Muhimbili university | Tanzania | English |
| Makerere university college | Uganda | English |

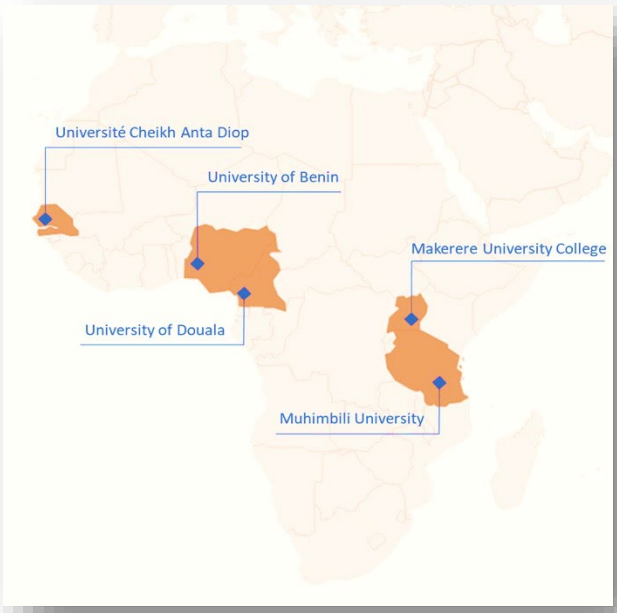


*Figure 1: Universities participating in the pilot phase*

This document serves as a tool for SF medical products education, which should be adapted to the needs of the university or training institution that uses the curriculum. It contains a competency framework and practical tips and is supplemented with six modules that are aligned with the WHO's prevention-detection-response strategy: introduction to SF medicines, identification of high-risk medicines, prevention of SF products in the supply chain, detection, reporting to appropriate regulatory authorities, and intervention to prevent patient harm.

# 2.Curriculum delivery

## 2.1. Objective and outcomes

**The goal of this project was to develop a training curriculum that will be included as a compulsory component within the undergraduate curriculum for pharmacists in the African region, available in both French and English and composed of hard and soft copy material**.

The curriculum includes detailed information relating to the root causes of SF medical products, the products most at risk, and early warning signals of their presence in the supply chain. SF medicines are often difficult to detect, even for trained professionals. They may not cause obvious adverse reactions but fail to treat conditions for which they were intended, often with serious consequences for the patient. Therefore, the modules will integrate training elements into the university curriculum to ensure that pharmacists know how to:

1. Identify medical products most at risk of being falsified;
2. Prevent SF medical products;
3. Detect SF medical products;
4. Report SF medical products; and
5. Intervene with advice for patients exposed to SF medical products.

As previously mentioned, the curriculum is to serve as a guide or framework that can be adapted to the needs of a specific university or class. In the pilot project, we found out that some universities have already covered some of the contents in related fields of study such as in quality assurance or patient safety courses. Universities should consider where there is need and how to fit in or adjust relevant content where needed. Therefore, it may become necessary to incorporate only relevant modules or sub-modules (see Appendix 1 for detailed descriptions of each module and sub-module under the Global Competency Framework for Pharmacists' Education and Training on Substandard and Falsified (SF) Medical Products) within the curriculum to ensure balance and effectiveness.

## 2.2 Teaching materials and methods

It is important to align this SF medicines curriculum with your university's existing curriculum to avoid duplication of material. Before implementing any changes, the SF curriculum should be mapped to the existing university curriculum.

Some universities may have already covered some of the SF contents in related fields of study, such as quality assurance or patient safety courses. Universities should consider where the content is needed, as well as how to fit in or adjust relevant content where needed. Therefore, it may become necessary to incorporate only relevant modules or sub-modules within the curriculum to ensure balance and effectiveness.

The curriculum is designed in a way that allows it to be taught to learners in stand-alone modular packages. The "adopt and adapt" principle is used to allow flexibility in how the curriculum can be applied in a specific context. Similar approach was successfully used with the 2012 International Pharmaceutical Federation (FIP) Global Competency Framework (GbCF).[12] It is also helpful for educators/trainers to assign equivalent levels of weight to modules based on local needs and priorities.

[12] International Pharmaceutical Federation (FIP). Global Competency Framework (GbCF). FIP, The Hague. 2012. Available from: https://www.fip.org/file/1412

The following teaching methods and training techniques can be used to deliver the curriculum depending on the learning objective, learning environment, audience and availability of technology.

It is important that curricula should incorporate pedagogical techniques and didactic methods. Therefore, this curriculum offers a combination of:

- Lectures;
- Case-studies with problem-solving exercises and case-based learning;
- Simulation and role-playing;
- Practical learning by doing;
- "Flipped" classroom;
- Workshops; and
- Project-based learning with creation of project reports, strategic papers and critical appraisal of literature.

One of the outcomes of this project was the development of the e-learning modules such as massive open online courses (MOOCs) and webinars. With increased access and utilisation of technology in education, these provide an alternate source of learning readily accessible from anywhere in the world.

The following teaching/learning materials are available to present the curriculum:

- References and links;
- PowerPoint slides;
- Notes;
- Handouts; and
- Videos.

This variety allows for flexibility in the curriculum delivery depending on the learning styles of the students.

The curriculum should also be assessed throughout its implementation to analyse whether it needs to be changed. As a result, students should be asked before starting each module to fill out an evaluation form, which assesses their competencies in that topic. After completion of a module, students should be asked to identify which aspects they found most and least valuable. A standard evaluation form or the evaluation system your university uses can be used.

Consider asking the students open-ended questions about whether:

- The module met their learning needs;
- There was sufficient opportunity for interaction and discussion; and
- The pace of module delivery was acceptable.

Students should also be asked to rate the following:

- The presenting skills of the trainer;
- The responsiveness of the trainer;
- The knowledge of the trainer;
- The balance of teaching methods;
- The practical exercises; and
- The training/learning resources.

By constantly assessing the performance of the curriculum, we can continue to improve it to better suit the needs of pharmacy education. The "Handbook for teachers" section below

delves more into step-by-step instructions and suggestions for successfully implementing the new curriculum.

## 2.3 Guide for teachers

### 2.3.1 Who is this guide for?

This curriculum guide serves as a handbook that aims to support educators and trainers of pharmacy undergraduates involved with the delivery of a SF medicines and medical products curriculum. It contains the syllabus (Appendix 1) and Global Competency Framework for Pharmacists' Education and Training on Substandard and Falsified (SF) Medical Products (Appendix 2), which are intended to serve as a reference for educators and learners to help ensure that pre-service education equips pharmacy undergraduates with an up-to-date syllabus and the requisite competencies to address SF medicines.

### 2.3.2 What is this guide for?

This guide provides educators and trainers with teaching materials, resources and practical guidance on preparing pharmacy undergraduates for practice with the relevant competencies for SF medical products. It should be used to support those undertaking the train-the-trainer course in SF medical products.

### 2.3.3 How do I use this guide?

The guide is intended to be a flexible resource. You can use sections of the guide to support existing learning programmes or activities which you currently deliver within your curriculum, or plan specific programmes depending on local or individual needs. The content is broken down into six modules (see Table 1).

*Table 1. SF medical product modules*

| Module | Title |
|---|---|
| A | Introducing the problem of SF medicines |
| B | How to identify medical products most at risk of being falsified |
| C | How to prevent SF medical products from entering the supply chain |
| D | How to detect SF medical products |
| E | How to report SF medical products |
| F | How to advise patients exposed to SF medical products |

Each module has:

- An aim;
- Embedded PowerPoint presentations;
- Learning outcomes for trainers;
- Suggested pre-module preparation;
- References and links;
- Student learning needs (including knowledge, skills and attitudes);
- Learning delivery/session plans with activities and delivery times;
- Handouts;
- Assessment; and
- Evaluation.

You can deliver the modules as separate sessions or combine them.

### 2.3.4 Who is your target audience?

Pharmacy undergraduates.

# 3. The train the trainer SF medical products programme

This programme will help you to plan and deliver the modules in the SF medical products curriculum depending on your context, your learners and the time you have available. The success of the SF medical products programme of learning depends on the extent to which it responds to the needs of the learners as well as the needs of the curriculum. The programme should be delivered to ensure there are opportunities for group interaction, allowing both students and educators/trainers to take part in the training and learn from one another. You should start with Module A, but Modules B–F can be delivered in any order. This guide also contains the Train the trainer delegate sign-up form (Appendix 3) and Train the trainer delegate evaluation form (Appendix 4) that can be used for similar train the trainer workshop preparation.

## 3.1 Aim and vision

*To enable educators and trainers to deliver a substandard and falsified medicines training curriculum for pharmacy students*

The curriculum includes detailed information relating to the root causes of SF medical products, the products most at risk and early warning signals of their presence in the supply chain. SF medical products are often difficult to detect, even for trained professionals. They may not cause obvious adverse reactions but fail to treat conditions for which they were intended, often resulting in serious consequences for the patient. WHO data show that healthcare professionals often report the most serious incidents, but they do not frequently report less serious cases and, if they do, it is at a late stage rather than early on. The SF medical products curriculum will teach pharmacy students on how to avoid, detect and report SF medicines, and how to advise affected patients and consumers.

The curriculum also covers procurement of medicines, conducting due diligence on supply sources, reporting through national regulatory authorities, and risk communication.

## 3.2 Overall learning outcomes for SF medical products: Train the trainers

1. List your learning needs for SF learning delivery;
2. Outline the curriculum for SF medical products;
3. Explain the syllabus and competency framework and how it should be used;
4. Utilise a framework for adapting a training session;
5. Plan training activities that facilitate students to achieve the competencies;
6. Plan how to assess and evaluate immediate learning about SF medicines;
7. Learn from peers through discussion of the learning delivery and materials;
8. Revisit the SF medical products content and training process with the eyes of a trainer; and
9. Describe effective ways to engage with learners about SF medicines, including answering questions, asking the right questions, fostering thought-provoking conversations and getting everyone to participate.

## 3.3 Overview of areas of learning: Train the trainers

### 3.3.1 Contextual background

Recognising that substandard and falsified (SF) medical products are an unacceptable public health threat, the WHO and its member states have developed a holistic prevention-detection-

response strategy to address the issue. Within the prevention pillar, quality ought to be demanded at all levels to guarantee supply chain integrity and product quality. This requires full engagement of those healthcare professionals who work closest to medical products and patients, namely, pharmacists.

Currently, in sub-Saharan Africa, there is no standardised, formal or harmonised university training for pharmacists dedicated to SF medical products. This region, whose population is most vulnerable to these products, is also that in which the WHO technical unit has conducted most activities in close collaboration with national regulatory authorities, making it the most logical location to pilot this project. There is a clear need for comprehensive and multidisciplinary training in SF medical products for pharmacists. Therefore, FIP together with the WHO developed a compulsory education component on SF medical products in four African countries as part of a pilot project.

The curriculum is to be used as training material about SF medical products and will be incorporated into the pharmaceutical university curriculum in the African region. It is designed to increase and improve the education and awareness levels of pharmacists in order to better prevent SF medical products reaching patients.

### 3.3.2 Learning outcomes for pharmacy undergraduates

Training elements (see Table 2) are integrated into the university curriculum teaching pharmacy and will ensure that pharmacists know how to:

1. Identify medical products most at risk of being falsified;
2. Prevent SF medical products;
3. Detect SF medical products;
4. Report SF medical products; and
5. Intervene with advice for patients exposed to SF medical products.

*Table 2. Learning outcomes through knowledge, skills and attitudes*

| | *Pharmacy students' training* |
|---|---|
| *Knowledge* | To gain the knowledge and awareness of substandard and falsified (SF) medical products, the factors that indicate risk, and the ways in which SF medicines can be detected and reduced. |
| *Skills* | To facilitate skills-based learning on how to:<br>1. Identify medical products most at risk of being falsified;<br>2. Prevent SF medical products;<br>3. Detect SF medical products;<br>4. Report SF medical products; and<br>5. Intervene with advice for patients exposed to SF medical products. |

| | |
|---|---|
| *Attitudes* | To promote the development of appropriate attitudes for combating SF medical products through training. |

### 3.3.3 Syllabus and competency framework

The syllabus and the Global Competency Framework for Pharmacists' Education and Training on Substandard and Falsified (SF) Medical Products are intended to serve as a reference for educators and learners to help ensure that pre-service education equips pharmacy undergraduates with an up-to-date syllabus and the requisite competencies to address SF medicines.

The competency framework is designed to improve awareness and understanding of SF medical products. It mainly acts as a menu of core knowledge, skills and attitudes relating to SF medical products for pharmacy undergraduates. Its aim is to ensure pharmacists are equipped with the requisite competencies (at the pre-service level) to address SF medical products in policy and practice settings. The competency framework is not intended as a defined scope of practice. Competencies should be interpreted and applied in the context of the defined roles and responsibilities in a specific jurisdiction, according to local regulations and practices. The full competency framework is available in Appendix 1.

### 3.3.4 Teaching/learning delivery — how to implement the SF medical products curriculum?

It is important to align this SF medicines curriculum with your university's existing curriculum so that duplication is avoided. Before implementing any changes, map the SF curriculum to the existing pharmacy curriculum.

Some universities may have already covered some of the SF curriculum contents in related fields of study, such as in quality assurance or patient safety courses. Universities should consider where the content is needed and how to fit in or adjust relevant content where needed. Therefore, it may become necessary to incorporate only relevant modules or sub-modules within the curriculum to ensure balance and effectiveness.

The curriculum is designed in a way that allows it to be taught to learners in stand-alone modular packages. The "adopt and adapt" principle is used to allow flexibility in how the curriculum can be applied to a specific context. It is also helpful for educators/trainers to assign the equivalent levels of weight to modules based on local needs and priorities.

### 3.3.5 Teaching/learning approach for SF medical products

The general suggested approach is classroom-based learning (with skills/attitudes practical sections). This can be supported by distance learning, experiential learning (at practice placements), self-study and blended learning (combining several of the aforementioned approaches). The overall approach you take will depend on available resources (e.g., e-learning) and constraints. You can adapt the approach so that it allows for all the learning activities and enough practice and feedback for learners.

**Classroom-based learning** — is classroom or lecture style teaching alongside printed education materials. This can be coupled with practical projects.
**Distance learning** — includes online modules, DVDs, videos and other non-face-to-face education methods, supplement or substitute for classroom methods.

**Experiential learning** — involves experiencing, observing, conceptualising and retrying activities. This differs from theory-based learning because it is case-based rather than concept-based and requires hands-on practice and reflection.

### 3.3.6 Teaching/learning activities for SF medical products

It is important to plan how you will deliver the learning activities, and to decide what learning materials you will use and the approach you will take for each module. Suggestions are given during the train-the-trainer course. However, you may want to adapt these to fit your local circumstances, considering the resources you have and the requirements and characteristics of your learners. The learning activities and approach have been designed to align with the competencies. It is also useful to create learning outcomes based on the competencies.

Examine the knowledge, skills and attitudes and decide if you need to adapt the corresponding suggested learning activities. Learning activities with the features listed below encourage learning if:

- They are appropriate for your local context;
- They allow enough practice and feedback to develop the required competencies;
- They allow learners to work with new information, situations or experiences (the learning activity requires learners to use the knowledge, skills or attitudes they are learning);
- Learners have opportunities to practise solving problems;
- Learners receive specific feedback as soon as practical after performing a skill or displaying attitudes and have an opportunity to reflect on and improve their practice; and
- Learners are encouraged to reflect on their learning.

The following learning activities (see Table 3) can be used to deliver the curriculum depending on the competencies, learning environment, learner requirements and availability of technology.

*Table 3. Learning activities for the SF medical product curriculum*

| **Adapting learning activities*** | | |
|---|---|---|
| *Type of knowledge, skill or attitude* | *Examples* | *Suggested learning activities* |
| Information | Describes what SF medical products are, explain the correct terminology, the extent of the problem and the concept of the fight against SF medical products. | Studying reference sources;<br>Lectures;<br>Online lectures;<br>Group projects (creation of project reports, strategic papers and critical appraisal of literature). |
| Decision making or problem-solving skills | Decide whether QC lab tests are needed for a suspected SF medical product.<br>Decide how to provide pharmaceutical care to a patient who has received a suspected SF medical product. | Discussions leading to making consensus decisions;<br>Case studies;<br>Problem-solving exercises;<br>Making a pharmaceutical care plan;<br>Reflective accounts. |
| Interpersonal skills and attitudes | Show empathy and respect when dealing with patients;<br>Communicate clearly; | Reflection on experiential learning;<br>Group activities about attitudes; |

| | | |
|---|---|---|
| | Work collaboratively with colleagues. | Brainstorming;<br>Discussion;<br>Role play/simulation. |

*adapted from Learning for Performance

### 3.3.7 Teaching/learning materials for SF medical products:

Learning materials are described based on the learning activities. Again, you may wish to adapt these to fit your local circumstances. References, links, videos and PowerPoint slides can be applied as a stimulus material for group discussions or role play descriptions. Learners can also learn how to use checklists (such as the one for visually inspecting suspect SF medical products), and complete reports (e.g., notifying the relevant national regulatory authority of a SF medical product). Handouts can be used for reflective practice or to support learning activities, e.g., identifying SF medical products from photographs. E-learning can be useful for self-paced learning or combined with lectures led by trainers. Online discussion groups can support learning and provide information and advice.

### 3.3.8 Preparing to deliver the learning approach, activities and materials

You can take the following steps to deliver the learning approach, activities and materials:

1. Identify the suggested and/or adapted materials that you can use as references while implementing the modules.
2. Develop/review the lesson plan — a set of instructions for delivering the module and enabling the learners to meet the competencies. This may include instructions for the educator/trainer, the learners, a supervisor or an assistant/demonstrator. Lesson plans can be adapted from the train-the-trainer modules which have the following structure:

- Aim;
- Learning outcomes;
- Pre-module preparation;
- References and links;
- Module overview;
- Module syllabus;
- Module competencies;
- Learning method;
- Learning materials and resources;
- Description of learning activities;
- Time for each activity;
- Assessment; and
- Evaluation.

3. Obtain the learning materials for each learning activity within the module.
4. Obtain assessment materials if required.
5. Obtain evaluation materials.

### 3.3.9 Assessment delivery — how do we assess competency?

Students will be assessed on the competencies they acquire through this curriculum. There is a mandatory part for all universities that deploy the curriculum, to be complemented by a non-compulsory part that can be added as needed.

There are two types of assessment: formative and summative. Formative assessment is primarily developmental, with a focus on providing feedback to support students' improvement. Summative assessment has a formative purpose too, but it is also used to measure students' learning against the intended learning outcomes.

### Mandatory assessment

At the beginning of the course, a formative assessment of students will look at their strengths and weaknesses. Themes that emerge from an evaluation of the collated strengths and weaknesses will inform trainers/educators about areas to focus on. At the end of the course, a summative assessment of students will look at the competencies acquired in knowledge, skills and attitudes. A unified multi-choice online questionnaire is used for this purpose.

For these assessments, the trainer/educator should ask the students to take the test all at the same time via an online form — in the computer room (or similar) at the university — and check that students work individually and do not consult each other or their notes.

### Selecting assessment methods

Select assessment methods that measure the specified competencies within each module. Table 4 describes how competencies can be assessed based on the type of performance required.

*Table 4. Assessment methods for SF medical products curriculum*

| Type of performance | Assessment method | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Written exam | Learner interview (oral exam) | Learner questionnaire | Observation (role play/ simulation) | Observation (in practice) | Project report | Learner action plan | OSCEs | Portfolios |
| Information recall (recalling facts, principles, numbers, process steps); usually required to inform decision-making skills. | √ | √ | √ | | | √ | | √ | √ |
| Decision-making and problem-solving skills (analysing a case study or situation and drawing conclusions). | √ | √ | √ | √ | √ | √ | √ | √ | √ |
| Applying skills or knowledge to a new situation (e.g. making a pharmaceutical care plan). | | √ | √ | √ | √ | | | | |
| Attitudes (behaviours that can be observed e.g. positive approach to combatting SF medical products). | | √ | √ | √ | √ | √ | √ | √ | √ |

Check that assessment methods are practical for the available resources and the specific competencies. For example, if practice-based placements are not possible, role play or simulation can be used instead, e.g., it may be more practical to observe counselling skills using a checklist during a role play or plan a practice-based observation of skills after the modules have been delivered.

## 3.4 What resources do SF medical product trainers have to learn about curriculum delivery?

**Resources available include:**

- **Live online interactive webinars —** presentations and discussions.
- **Self-directed learning —** recorded webinars, references and links to resources.
- **Group learning** — educators and trainers will be able to access live sessions where you can learn, network and collaborate as a group.
- **At your university** — trainers should engage peers and students at their workplace to undertake their learning activities as part of the train-the-trainer programme.

## 3.5 Who is involved?

A group of experts has developed the SF medical products curriculum. This underpins the train-the-trainer programme.

Further reading: The Capacity Project. Learning for Performance. A Guide and Toolkit for Health Worker Training and Education Programs. IntraHealth International, Capel Hill, North Carolina, USA. 2007.

# 4. Detailed overview of the modules

The modules A-F are corresponding to the Global Competency Framework for Pharmacists' Education and Training on Substandard and Falsified (SF) Medical Products (see Appendix 1). They are designed as ready to implement teaching materials in the practical form of power point slides. Under the "adopt and adapt" principle, they can be adopted by teachers and institutions and adapted based on their teaching or educational needs. They are available upon request at the International Pharmaceutical Federation. This Guide presents the overview of how the modules can be used, together with additional information on pre-modules preparation and list of references and further readings. The syllabus included in Appendix 1. The exercises to support the delivery of the modules is included in Appendix 2.

## 4.1 Module A — Introducing the problem of SF medicines

### 1. Aim

To explore how to introduce the problem of SF medicines and discuss the learning delivery of this topic and assessment of learning.

### 2. Learning outcomes for trainers:

1. Outline the syllabus and competencies;
2. Plan how to deliver the learning approach and activities;
3. Identify and use learning materials; and
4. Plan for delivering assessments (formative and summative).

### 3. Suggested pre-module A preparation

*Exercise*

Prepare the outline of a classroom activity that develops some of the Module A knowledge, skills and attitudes listed for pharmacy undergraduates.

### 4. Module A overview

Module A will cover a general introduction to the problem of SF medical products. It is divided into the following topics:

A.1. Definitions;
A.2. Why is it a problem?;
A.3. Legislation and regulation;
A.4. Integrity of the supply chain and concerned stakeholders; and
A.5. Advocacy and initiatives at national, regional and international level.

### 5. Module A syllabus

Please refer to the syllabus outline under the Competency Framework.

### 6. Module A learning outcomes for pharmacy undergraduates — competencies:

Please refer to the overview of competencies acquired through knowledge, skills and attitudes under the Competency Framework.

### 7. General overview of Module A

Table 5 below shows a General overview of module A that can be adapted for train the trainers workshops.

*Table 5. General overview of module A, Train the trainer*

| Content | Activity | Resources |
|---|---|---|
| Welcome and introductions<br>Structure of the train-the-trainer programme<br>Overall learning outcomes for trainers<br>Contextual background<br>Aim and vision of curriculum<br>Syllabus and competency framework<br>Delivering the learning<br>Assessment and evaluation | Presentation<br>Group discussion — trainers are asked to share their reason for attending the course and their experience of teaching in this or a related area.<br>Group discussion to clarify and agree if any additional learning needs to be included in the programme. | General overview slide deck<br>Trainer's handbook |
| Aim and learning outcomes for trainers<br>Overview of module A<br>Module A competencies for pharmacy undergraduates<br>Learning method/delivery | Presentation | Module A slide deck |
| Module A.1 and A.2<br>Practical learning activity | Presentation<br>Group discussion of pre-module A exercise | |
| Module A.3, A.4 and A.5 | Presentation<br>Group discussion — what might be useful to discuss with students? | |
| Assessment | Group discussion — what methods of formative and summative assessment could be used? | |
| Evaluation/reflection | Group discussion —<br>• main learning points<br>• changes in practice<br>• additional learning needs<br>Individuals to complete evaluation form | |

## 8. References and further readings:


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## 4.2 Module B — How to identify medical products most at risk of being falsified

### 1. Aim

To explore how to introduce the problem of SF medicines and discuss the learning delivery of this topic and assessment of learning.

### 2. Learning outcomes for trainers:

1. Outline the syllabus and competencies;
2. Plan how to deliver the learning approach and activities;
3. Identify and use learning materials;

4. Plan to deliver an assessment.

## 3. Suggested pre-module B preparation

*Exercise*
Describe a problem-based learning project that pharmacy undergraduates can undertake to demonstrate one or more of the skills they need to develop for this module.

## 4. Module B overview
Module B will cover identification of SF medical products most at risk of being falsified. It is divided into the following topics:

B.1. Scale of the problem
B.2. Motivation of SF medical products industry
B.3. Common cases and factors contributing to the problem of poor access to health care
B.4. Characteristics of products at risks
B.5. Where to find information

## 5. Module B syllabus
Please refer to the syllabus outline under the Competency Framework.

## 6. Module B learning outcomes for pharmacy undergraduates — competencies:
Please refer to the overview of competencies acquired through knowledge, skills and attitudes under the Competency Framework.

## 7. General overview of Module B
Table 6 below shows a General overview of module B that can be adapted for train the trainers workshops.

*Table 6. General overview of module B, Train the trainer*

| Content | Activity | Resources |
|---|---|---|
| Welcome and introductions<br>Aim and learning outcomes for trainers<br>Overview of module B<br>Module B competencies for pharmacy undergraduates<br>Learning method/delivery | Presentation | Module B slide deck |

| | | |
|---|---|---|
| Module B1 and B2 | Presentation<br>Group discussion of pre-module B exercise | |
| Module B3, B4 and B5 | Presentation<br>Group discussion — what might be useful to discuss with students? | |
| Practical learning activity | Group discussion of pre-module B exercise | |
| Assessment | Group discussion — what methods of formative and summative assessment could be used? | |
| Evaluation/reflection | Group discussion —<br>• main learning points;<br>• changes in practice;<br>• additional learning needs.<br>Individuals to complete evaluation form | |

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## 4.3 Module C — How to prevent SF medical products from entering the supply chain

### 1. Aim
To explore the content of the module on preventing SF medical products entering the supply chain and discuss how learning can be delivered and assessed.

### 2. Learning outcomes for trainers:
1. Outline the syllabus and competencies;
2. Plan how to deliver the learning approach and activities;
3. Identify and use learning materials; and
4. Plan an assessment.

### 3. Suggested pre-module C preparation

**Exercise**
Outline a simulation or experiential learning approach for compounding medicines.

### 4. Module C overview
Module C will cover how to prevent SF medical products from entering the supply chain. It is divided into the following topics:

C.1. Safe procurement;
C.2. Safeguarding the supply chain;
C.3. Awareness; and
C.4. The role of pharmacists in the education of patients.

### 5. Module C syllabus
Please refer to the syllabus outline under the Competency Framework.

### 6. Module C learning outcomes for pharmacy undergraduates — competencies:
Please refer to the overview of competencies acquired through knowledge, skills and attitudes under the Competency Framework.

## 7. General overview of Module C

Table 7 below shows a General overview of module C that can be adapted for train the trainers workshops.

*Table 7. General overview of module C, Train the trainer*

| Content | Activity | Resources |
|---|---|---|
| Welcome and introductions<br>Aim and learning outcomes for trainers<br>Overview of module C<br>Module C competencies for pharmacy undergraduates<br>Learning method/delivery | Presentation | Module C slide deck |
| Module C.1 and C.2 | Presentation<br>Group discussion of pre-module C exercise | |
| Module C.3 and C.4 | Presentation<br>Group discussion — what might be useful to discuss with students? | |
| Practical learning activity | Group discussion of pre-module C exercise | |
| Assessment | Group discussion — what methods of formative and summative assessment could be used? | |
| Evaluation/reflection | Group discussion —<br>• main learning points;<br>• changes in practice;<br>• additional learning needs.<br>Individuals to complete evaluation form | |

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## 4.4 Module D — How to detect SF medical products

### 1. Aim
To explore the content of the module on how to detect SF medical products and discuss how learning can be delivered and assessed.

### 2. Learning outcomes for trainers:
1. Outline the syllabus and competencies;
2. Plan how to deliver the learning approach and activities;
3. Identify and use learning materials and resources; and
4. Plan and deliver an assessment.

### 3. Suggested pre-module D preparation

**Exercise**
Outline a simulation or case study that develops pharmacy undergraduate competencies in recognising SF medical products by visual and physical inspection.

### 4. Module D overview
Module D will cover detection of SF medical products. It is divided into the following topics:

D.1. Detection strategies;
D.2. Link to quality control;
D.3. Link to pharmacovigilance; and
D.4. Technology.

### 5. Module D syllabus
Please refer to the syllabus outline under the Competency Framework.

### 6. Module D learning outcomes for pharmacy undergraduates — competencies:
Please refer to the overview of competencies acquired through knowledge, skills and attitudes under the Competency Framework.

### 7. General overview of Module D
Table 8 below shows a General overview of module D that can be adapted for train the trainers workshops.

*Table 8. General overview of module D.*

| Content | Activity | Resources |
|---|---|---|
| Welcome and introductions<br>Aim and learning outcomes for trainers<br>Overview of module D<br>Module D competencies for pharmacy undergraduates<br>Learning method/delivery | Presentation | Module D slide deck |
| Module D.1, D.2 and D.3 | Presentation<br>Group discussion of pre-module D exercise | |
| Module D.4 | Presentation<br>Group discussion — what might be useful to discuss with students | |
| Practical learning activity | Group discussion of pre-module D exercise | |
| Assessment | Group discussion — what methods of formative and summative assessment could be used? | |
| Evaluation/reflection | Group discussion —<br>• main learning points;<br>• changes in practice;<br>• additional learning needs.<br>Individuals to complete evaluation form | |

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# 4.5 Module E — How to report SF medical products

### 1. Aim
To explore the content of the module on how to report SF medical products and discuss how learning can be delivered and assessed.

### 2. Learning outcomes for trainers:
1. Outline the syllabus and competencies;
2. Plan how to deliver the learning approach and activities;
3. Identify and use learning materials and resources; and
4. Plan and deliver an assessment.

### 3. Suggested pre-module E preparation

**Exercise**
Outline a classroom activity where pharmacy graduates need to report a SF medical product to their national regulatory authority.

### 4. Module E overview

Module E will cover the process of reporting SF medical products. It is divided into the following topics:

E.1. Reporting to relevant authorities (Who? Where? When? To whom? What?);
E.2. Reporting up the supply chain;
E.3. Systematic sharing of data; and
E.4. Developing reporting systems.

### 5. Module E syllabus
Please refer to the syllabus outline under the Competency Framework.

### 6. Module E learning outcomes for pharmacy undergraduates — competencies:
Please refer to the overview of competencies acquired through knowledge, skills and attitudes under the Competency Framework.

### 7. General overview of Module E
Table 9 below shows a General overview of module E that can be adapted for train the trainers workshops.

*Table 9. General overview of module E, Train the trainer*

| Content | Activity | Resources |
|---|---|---|
| Welcome and introductions<br>Aim and learning outcomes for trainers<br>Overview of module E<br>Module E competencies for pharmacy undergraduates<br>Learning method/delivery | Presentation | Module E slide deck |
| Module E1, and E2 | Presentation<br>Group discussion of pre-module E exercise | |
| Module E3 and E4 | Presentation<br>Group discussion — what might be useful to discuss with students? | |
| Practical learning activity | Group discussion of pre-module E exercise | |
| Assessment | Group discussion — what methods of formative and summative assessment could be used? | |
| Evaluation/reflection | Group discussion —<br>• main learning points;<br>• changes in practice;<br>• additional learning needs.<br>Individuals to complete evaluation form | |

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# 4.6 Module F — How to advise patients exposed to SF medical products

### 1. Aim
To explore the content of the module on how to advise patients exposed to SF medical products and discuss how learning can be delivered and assessed.

### 2. Learning outcomes for trainers:
1. Outline the syllabus and competencies;
2. Plan how to deliver the learning approach and activities;
3. Identify and use learning materials and resources; and
4. Plan an assessment.

### 3. Suggested pre-module F preparation

**Exercise**
Create a practical exercise that develops one or more of the Module F skills required by pharmacy graduates.

### 4. Module F overview
Module F will cover how to advise patients exposed to SF medical products. It is divided into the following topics:

F.1. How to intervene in different situations: consuming SF medical products;
F.2. Effects on the patient;
F.3. How to proceed with patients to ensure treatment continuity in case of SF medical products; and
F.4. Communication of information to colleagues and regulators.

### 5. Module F syllabus
Please refer to the syllabus outline under the Competency Framework.

### 6. Module F learning outcomes for pharmacy undergraduates — competencies:
Please refer to the overview of competencies acquired through knowledge, skills and attitudes under the Competency Framework.

### 7. General overview of Module F
The table below shows a General overview of module F that can be adapted for train the trainers workshops.

*Table 10. General overview of module F, Train the trainer*

| Content | Activity | Resources |
|---|---|---|

| | | |
|---|---|---|
| Welcome and introductions<br>Aim and learning outcomes for trainers<br>Overview of module F<br>Module F competencies for pharmacy undergraduates<br>Learning method/delivery | Presentation | Module F slide deck |
| Module F.1, F.2 and F.3 | Presentation<br>Group discussion of pre-module F exercise | |
| Module F.4 | Presentation<br>Group discussion — what might be useful to discuss with students? | |
| Practical learning activity | Group discussion of pre-module F exercise | |
| Assessment | Group discussion — what methods of formative and summative assessment could be used? | |
| Evaluation/reflection | Group discussion —<br>• main learning points;<br>• changes in practice;<br>• additional learning needs.<br>Individuals to complete evaluation form | |

## 8. References and further readings:


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- Picker Institute. Principles of patient-centered care. 1987. Available at: http://pickerinstitute.org/about/picker-principles/.
- International Pharmaceutical Federation. Counterfeit medicines advice for healthcare professionals: Guidance for pharmacists and dispensing doctors. Available at: https://www.fip.org/files/fip/counterfeit/national/UKCounterfeitadvice209.pdf.

# 5.Conclusions

This publication is the result of wide ranging global and regional efforts and collaboration between the World Health Organization and the International Pharmaceutical Federation, with the support of leading global partners La Conférence Internationale des Ordres de Pharmaciens Francophones and Commonwealth Pharmacists Association. The five pilot universities in sub-Saharan Africa were crucial in the development of the curriculum and their role in deployment of this first-of-its-kind curriculum will be pivotal. With a growing need around the globe to combat the SF medical products, we expect a rising interest in adopting this curriculum in more countries in the African region and beyond.

This document covers a global gap and builds further on the newly developed Global Competency Framework for Pharmacists' Education and Training on Substandard and Falsified (SF) Medical Products that was developed as part of this project. It lays out learning objectives and outcomes as they pertain to the pharmacists practising in different settings. The development of this guide is in line with the WHO and WHO member states driven holistic prevention-detection-response strategy, to improve awareness and understanding of the SF medical products threat through effective communication, education and training. It is hoped that educators, faculties of pharmacy, training institutions, health regulatory institutions and other users will find it a useful resource in meeting their respective needs for strengthening pharmacists' contributions to containing SF medical products' threat to public health.

This curriculum guide aims to support the delivery of the curricula on SF medical products that will be incorporated into the pharmaceutical university curriculum in the African region. It facilitates the use of dedicated training materials that were carefully developed for this matter.

This curriculum guide was developed to support a bilingual curriculum. It is very opportune that both the Anglophone and Francophone curricula are based on the same needs and provide equal information to pharmacists across sub-Saharan Africa. This demonstrates that the response to SF medical products and respective training should be based on common grounds and enhanced collaboration.

We hope that this curriculum guide, the competency framework and the comprehensive curriculum training materials will help to increase and improve the education and awareness levels of pharmacists in order to better prevent SF medical products reaching patients.

# 6. Appendices

## 6.1 Appendix 1: Global Competency Framework for Pharmacists' Education and Training on Substandard and Falsified (SF) Medical Products and respective syllabus outline

The table 11 outlines the syllabus for undergraduate pharmacists with Modules A–F corresponding to the Global Competency Framework for Pharmacists' Education and Training on Substandard and Falsified (SF) Medical Products. The competencies are linked to the Global Competency Framework (GbCF) developed by FIP.[13] The competencies outlined in the GbCF are indicated with a respective corresponding number in the GbCF publication.

Table 11. Syllabus & Competency Framework

| Learning outcome | Syllabus outline | Competency framework — competencies acquired through knowledge, skills and attitudes |
|---|---|---|
| **Module A**<br><br>General intro-duction | **A.1 — Definitions** -<br><br>- Internationally accepted definitions led by the World Health Organization (WHO)<br>- Historical overview of how the language of the definitions shaped international collaboration<br>- Explanation of the evolution of the definitions: from the concept "counterfeit medicine" that has not facilitated the collaboration in the fight against SF medical products both internationally and within the same country, to the concept of "substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical product" that was more inclusive and enabled international collaboration, to the current simplified definition of "substandard and falsified (SF) medical products"<br>- Discussion of the legal implications of each definition, also leading to their evolution into "SF medical products"<br><br>**A.2 — Why is it a problem?**<br><br>- Fatal/damaging incidents examples<br>- Increasing globalisation and complexity of the supply chain increases risk for production errors or quality issues<br>- Mistrust in the health system, public health institutions and in healthcare professionals<br>- Propagation of further criminal activity and corruption (funding criminal activities, corruption, weapons etc.) — victims may be unaware and consequently unable to seek government aid.<br>- SF medical products contributing to antimicrobial resistance<br>- Socio-economic/economic issues and social effect | **Knowledge:**<br>• Introduce global health architecture (definitions, limitations, scope of work)<br>• Describe what SF/counterfeit medical products are (differentiate between SF/counterfeit from public health perspective)<br>• Identify the extent of the problem of SF medical products incidents (explore SF medical products prevalence, variations in distribution globally and limitations/challenges of research defining the global burden)<br>• Describe the limitations and availability of data in some regions<br>• Demonstrate proficiency in the legal and regulatory framework that govern medicines internationally and locally<br>• State the definition of patents and Trade-Related Aspects of Intellectual Property (TRIPS) legislation<br>• Explain how and where the integrity of the supply chain can be compromised<br>• Recognise the key actors and stakeholders in the SF medical products fight, the campaign against SF medical products and their responsibilities in the campaign<br>• Explain the definition and implementation of disciplinary or penal sanctions for health professionals involved in the introduction of SF medical products<br>**Skills:**<br>• Recognise the interaction of legislative, social and political factors in the emergence of SF medical products incidents |

[13] International Pharmaceutical Federation (FIP). Global Competency Framework (GbCF). FIP, The Hague. 2012. Available from: https://www.fip.org/file/1412

| Learning outcome | Syllabus outline | Competency framework — competencies acquired through knowledge, skills and attitudes |
|---|---|---|
| | **A.3 — Legislation and regulation**<br><br>- Introductions to the pharmaceutical supply chain<br>- Weaknesses where SF medicines can enter the supply chain, and strategies to combat these<br>- WHO guidelines and standards on regulation and quality of pharmaceutical products: Good Manufacturing Practices, Good Storage Practices and Good Distribution Practices<br>- Legislation enacting or strengthening the combating of SF related crime, United Nations Office on Drugs and Crime Good Guide for Legislation<br><br>Examples of ongoing legislative processes to combat SF medical products in Africa:<br><br>- Institute of Research Against Counterfeit Medicines "Contribution to the development of the Model Law on the Prevention and Punishment of Offenses relating to the Falsification of Medical Products and Similar Crimes"<br>- Preliminary draft law on the prevention and repression of offences in the fight against the trafficking of fake drugs and other medical products in Burkina Faso<br>- National Agency for Food and Drug Administration (Nigeria) enforcement of mobile authentication scheme designed to curb SF medical products, primarily antimicrobials<br>- Ugandan government centralisation of vaccine and veterinary drug imports to allow the animal health commissioner to screen distributers to improve product standards<br>- "Sub-regional framework for the harmonization of offenses and sanctions related to the trafficking of medicines and other health products in the Economic and Monetary Community of Central Africa (CEMAC) zone" legislation, designed by the Organization of Coordination for the Fight Against Endemic Diseases in Central Africa to standardise penalties for SF medical product trafficking across the CEMAC zone<br><br>**A.4 — Preserving the integrity of the supply chain**:<br><br>- The role of:<br>• The public<br>• Civil society through organisations representing health professionals<br>• Patients<br>• Manufacturers<br>• Distributors<br>• Prevention and enforcement services (police, customs, justice)<br>• Media and governments.<br>• Medicines providers (end users, like retail pharmacy and hospitals)<br>- Structuring an action plan to ensure collaboration across all key shareholders<br><br>**A.5 — Advocacy and initiatives at national, regional and international levels**<br><br>- Introductions to advocacy and its importance<br>- Research and grey literature — introductions of the research perspectives (limitations)<br>- International policies and initiatives on combating SF medical products:<br>• 1951 Resolution ERB7.R79 of WHO — created more uniform methods of controlling medicines<br>• 1985 Conference of WHO experts in Nairobi — recommended collecting data on extent of medicines counterfeiting | • Effectively communicate about SF medical products and about the gravity of the problem with correct use of terminology<br>• Describe the concept of the fight against SF medical products<br>• Demonstrate leadership, governance and management skills<br>• Use appropriate communication skills to educate, build, report and engage with patients, health and social care staff and voluntary services (e.g. verbal and non-verbal) (GbCF 4.1.5)<br><br>**Attitudes:**<br>• Recognise the gravity and urgency of the SF medical products problem<br>• Demonstrate work ethics<br>• Show an enthusiastic approach to learning<br>• Demonstrate willingness to learn from other students or colleagues irrespective of grade level<br>• Demonstrate willingness to communicate with, guide, inform and educate other stakeholders<br>• Recognise personal and professional responsibilities to address the SF medical products<br>• Keep up to date with existing regulations and initiatives |

| Learning outcome | Syllabus outline | Competency framework — competencies acquired through knowledge, skills and attitudes |
|---|---|---|
| | • WHA adoption of WHA41.16 — initiated programmes for prevention and detection of SF medical products<br>• WHO & IFPMA collaborative workshop — formulated an agreement on the definition of "counterfeit" medical products<br>• WHA adoption of WHA47.13 — requested WHO assist countries in combating SF medical products<br>• IMPACT — a task force designed to facilitate international collaboration on combating counterfeit medicines<br>• Call of Cotonou — introduced SF medical products to the international spotlight<br>• MEDICRIME Convention - introduced a framework for improving awareness of SF medical product crime<br>• WHO Member State Mechanism - established a global platform for addressing SF medical products<br>• WHO Global Surveillance and Monitoring System — encouraged SF medical product reporting<br><br>- African regional policies and initiatives on combating SF medical products:<br>• West African Economic and Monetary Union (UEMOA) advocacy — developed a set of strategies to fight illicit drug markets and counterfeiting in UEMOA member states<br>• Round table of Ouagadougou — developed strategies to combat SF medical products in West Africa<br>• Declaration of Niamey of the First Ladies of Africa — developed a training programme for customs and police officers and improved public awareness on SF medical products<br>• Declaration of Addis Ababa — developed multidisciplinary enforcement mechanisms and improved coordination of regulatory organisations<br>• Douala Declaration (CEMAC) — developed commitments to implementing action plans against SF medical products in the CEMAC zone<br>• Final Declaration at the Bamako Summit for Partnership, Peace, and Emergence — allowed heads of state and government officials to see the need to invest in the health sector<br>• Call from Syracuse — experts appealed to the heads of governments in adopting comprehensive laws against SF medical products<br>• Rabat Resolution on the fight against falsified drugs in Africa — Ministries of Health pledged to provide resources and legislation to combat SF medical products<br><br>- Advocacy and initiatives of international non-governmental organisations contributing to the SF medicines fight: International Pharmaceutical Federation (FIP), Commonwealth Pharmacists Association (CPA), La Conférence Internationale des Ordres de Pharmaciens Francophones (CIOPF), International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Fight the Fakes Campaign | |
| **Module B**<br><br>Identify medical products most at risk | **B.1 — Scale of the problem**<br><br>- International<br>• Developed countries vs. developing countries<br>- Regional<br>• North Africa vs. sub-Saharan Africa<br>- National<br>- Local | **Knowledge:**<br>• Comprehend the drivers of SF medical products and socio-economic consequences<br>• Recognise the most at-risk products to be falsified and/or substandard<br>• Link different factors contributing to the problem<br>• State the purpose of international conventions on transnational crime/ harmonisation of punitive legislation<br>• Recognise the importance of health system strengthening |

| Learning outcome | Syllabus outline | Competency framework — competencies acquired through knowledge, skills and attitudes |
|---|---|---|
| | **B.2 — Motivation of SF medical products industry**<br><br>Factors that drive the SF medical product industry:<br><br>- Financial profits<br>• Inability to afford equipment and trained staff, compliance standards and expensive APIs may cause companies to seek out easy profits by producing SF medical products<br>- Inconsistent regulatory checks<br>• Weak regulatory structure due to complex legal framework, staff shortages and lack of funding<br>- Insufficient penalties<br>• Bribery and corruption of government officials leading to lenient penalties and allowing dealers to escape arrest<br>- Lobbying<br>• Current legislation in many countries does not differentiate counterfeiting medicines and other goods; therefore, a national action plan needs to be developed to promote new legislation and operating procedures to combat SF medical products<br><br>Legislative processes and initiatives across Africa:<br><br>- Coraq-lab project — programme implemented in Benin, Burkina Faso, Mauritania and Niger to strengthen quality assurance of the National Medicine Quality Control Laboratories<br>- Special anti-fake medicine brigade — a group developed in Guinea to combat SF medical product crime and protect public health<br>- Harmonised Common Technical Document — initiative adopted in West Africa to harmonise registration requirements across the region<br>- Medicrime convention — international treaty that established criminal offences for manufacturing, supplying and trafficking SF medical products<br>- The United Nations Office on Drugs and Crime report "Combating falsified medical product-related crime: A guide to good legislative practices" — provides guidance on improving legislative frameworks and enacting existing legislation to prevent SF related crime<br><br>**B.3 — Common cases and factors contributing to the problem**<br><br>Factors that contribute to the SF medical product industry:<br><br>- Access to health care<br>• Universal health coverage (UHC) — health service that ensures everyone receives quality and essential health care without financial hardship and maintains that medicines are inelastic goods (i.e., buyers will be less sensitive to higher prices)<br>• Lack of UHC drives unequal access to essential services, which allows population poverty and lack of education to lead to tolerated non-official markets<br>- Medicines shortages<br>• When the supply of medicines cannot meet their demand, medicine prices skyrocket and promote people to buy from unlicensed sources<br>• Shortages are a common entry point for SF medical products to permeate the supply chain<br>- Online market and illegal online pharmacies | **Skills:**<br>• Perform risk analysis of SF medical products problem in your country<br>• Lead critical inquiry and apply scientific method in managing SF medical products<br>• Demonstrate effective communication and interpersonal skills<br>• Demonstrate critical and innovative thinking and practice<br>• Exhibit leadership, management and governance in handling SF medical products issues<br><br>**Attitudes:**<br>• Perception of the scale and form of SF medical products<br>• Perform lifelong self-directed learning to keep up to date with most valid and factual information about the incidents involving SF medical products |

| Learning outcome | Syllabus outline | Competency framework — competencies acquired through knowledge, skills and attitudes |
|---|---|---|
| | • Increasing internet connectivity and authorisation of online medical purchases across the globe have led to an increased popularity for internet pharmacies<br>• Illegal online pharmacies and SF medical products<br>• Although the ".Pharmacy" domain in the USA and the EU common logo allow consumers to differentiate between licensed and unlicensed online pharmacies, the SF medical product industry has started to falsify these tools<br>- Local production weakness<br>• Although local production offers a variety of benefits, inexperienced staff, poor infrastructure, and lack of capital prevent developing countries from manufacturing medicines locally<br><br>Global efforts to combat SF medical products:<br><br>- Interpol<br>• Operation Pangea — international initiative launched in 2008 to combat sales of SF medical products online and raise awareness about online medicine purchases<br>• Operation Qanoon — regional initiative that targets illegal medical products in the Middle East and North Africa<br>• Operation Heera — regional initiative that targets trafficking of pharmaceutical products in West Africa<br>• Operation Rainfall — regional initiative that targets illegal medicine trafficking in Asia<br>- Pharmaceutical Security Institute (PSI) — international organisation consisting of pharmaceutical manufacturers that combat the SF medical product industry<br><br>**B.4 — Characteristics of products at risks**<br><br>- SF medical product targets differ between developed and developing countries<br>• Life-style medicines (slimming pills, hormones, or steroids) are often the target in developed countries, whereas life-saving medicines (antibiotics and antimalarials) are targeted in developing countries<br>• Medical devices are also commonly affected across both developed and developing countries<br><br>- Although the SF medical product industry targets every kind of medical product, they most routinely target:<br>• Antimalarials<br>• Antibiotics<br>• Vaccines<br>• HIV treatments<br>• CNS medicines<br>• Cardiovascular medicines<br>• Antidiabetics<br>• Anticancer medicines<br><br>- Global Surveillance and Monitoring System (GSMS) Product Alerts are released to protect public health by notifying the population of a safety issue with a medical product<br>• Reserved for drugs that either present life-threatening risk to health or some form of harm<br>• Translated into six UN languages | |

| Learning outcome | Syllabus outline | Competency framework — competencies acquired through knowledge, skills and attitudes |
|---|---|---|
| | • Can be used to help create watch lists, allowing for the identification of products at risk and targeting market surveillance<br><br>**B.5 — Where to find information**<br><br>Resources to find factual, reliable information regarding SF medicines:<br><br>- WHO<br>• Official website<br>• Full List of Medical Product Alerts<br>• Report on the WHO global surveillance and monitoring system for substandard and falsified medical products<br>• A study on the public health and socioeconomic impact of substandard and falsified medical products<br>- EMA<br>• Official website<br>• Falsified medicines: overview<br>- FDA<br>• Official website<br>• Counterfeit medicine article<br>- The Pharmaceutical Security Institute website<br>- International Institute of Research Against Counterfeit Medicine website<br>- International Federation of Pharmaceutical Manufacturers & Associations<br>- Interpol: International crime operations<br>- Scholarly articles | |
| Module C<br><br>Prevent SF medical products | **C.1 — Safe procurement**<br><br>- Globalisation of the supply chain<br>• Improved technology, transportation, and communication have led to an increasingly complex supply chain that could involve several companies in a variety of countries<br>• Despite increasing complexity, globalisation has led to increased medicine availability, economic growth and lower labour costs<br>- Complexity and challenges in the modern supply chain<br>• Increasing the number of companies that are involved in the supply chain has increased the opportunities for mistakes and SF medical product infiltration — large supply chains require extensive coordination and inventory management systems that are not easily achieved<br>• Dependence on foreign production chains can increase the delivery time for medicines and can compromise availability<br>- Examples of the supply chain across the world<br>- Medicines procurement<br>• Determine the drug products needed<br>• Decide on an approved, reliable vendor/source — local vendors often reduce the risk of medicine shortages and SF infiltration<br>• Evaluate and determine the best drug product price<br>• Complete a purchase order<br>• Deliver the purchase order | **KNOWLEDGE:**<br>• Appropriately validate prescriptions, ensuring that prescriptions are correctly interpreted and legal (GbCF 2.3.3)<br>• Appropriately select medicines (e.g., according to the patient, hospital, government policy, etc) (GbCF 2.1.1)<br>• Know principles of effective pharmaceuticals and health supplies chain management such as Good Manufacturing Practice/sterile production and good governance/regulatory aspects<br>• Know all the requirements of good professional practice to prevent the introduction of SF medical products<br>• Identify how to prequalify suppliers at all pharmaceuticals chain levels<br>• Ensure accurate verification of rolling stocks (GbCF 3.5)<br>• Ensure effective stock management and running of service with the dispensary (GbCF 3.5)<br>• Ensure logistics of delivery and storage (GbCF 3.5)<br>• Demonstrate knowledge in storing medicines to minimise errors and maximise accuracy<br>• Take responsibility for quantification of forecasting (GbCF 3.5)<br>• Access reliable information and ensure the most cost-effective medicines in the right quantities with the appropriate quality (GbCF 3.4.1)<br>• Develop and implement contingency plan for shortages (GbCF 3.4.2) |

| Learning outcome | Syllabus outline | Competency framework — competencies acquired through knowledge, skills and attitudes |
|---|---|---|
| | • Inspect the drug products upon receiving them<br>• Approve the written invoice and provide payment<br>• Maintain proper records of purchase history<br>- Storage<br>• Proper storage is required to maintain therapeutic efficacy across a variety of drug products<br>• WHO guidelines on Good Storage Practices, including content on storage areas, containers, labelling, recalls, SF medical product infiltration and record keeping<br><br>**C.2 — Safeguarding the supply chain**<br><br>- Pharmaceutical Industry Principles for Responsible Supply Chain Management<br>• Guidelines formulated by the pharmaceutical supply chain initiative to ensure an ethical, safe, and healthy working environment<br>- The role of the pharmacist in the supply chain<br>• Pharmacists are employed throughout all parts of the supply chain, with some countries requiring pharmacist involvement in drug procurement, storage or dispensing<br>- Good Manufacturing Practice (GMP)<br>• A set of measures that ensure manufacturing processes are defined, create consistent, quality products, undergo qualification and validation, and are well-documented<br>• Primarily designed to reduce risks, GMP also reduces SF infiltrations<br>• WHO provides detailed guidelines on GMP, but many countries have also formulated their own GMP guidelines based on WHO GMP<br>- Good Distribution Practice (GDP)<br>• Designed to ensure the quality of a medical product throughout the distribution process, GDP acts as a tool to prevent SF infiltration<br>• WHO provides detailed guidelines on GDP, but differed distribution models are used in different countries<br>• The Expert Committee on Specifications for Pharmaceutical Preparation of WHO adopted the Model Quality Assurance System for Procurement Agencies (MQAS), which created a quality assurance system and resulted in procuring high-quality medical products<br><br>**C.3 — Awareness**<br><br>- Raising public awareness and education are important, as many patients feel as though they do not have enough information about SF medical products<br>• Many strategies are available to raise awareness, including focusing target groups, available communication channels, or specific persons in the community<br>• Some of the most important topics in health care include discussing medicines quality, affordability and availability<br>- Pharmacy associations are often involved in campaigns to raise awareness, including:<br>• Fight the Fakes — campaign whose goal is to raise awareness about the dangers of SF medical products<br>• International Pharmaceutical Federation — global pharmacy association that has been speaking out and promoting activism against the SF medical industry for more than 20 years | • Efficiently link procurement to formulary, to push/pull system (supply chain management) and payment mechanisms (GbCF 3.4.3)<br>• Ensure there is no conflict of interest (GbCF 3.4.4)<br>• Select reliable supplier of high-quality products (including appropriate selection process, cost effectiveness, timely delivery) (GbCF 3.4.5)<br>• Supervise procurement activities (GbCF 3.4.6)<br>• Understand the tendering methods and evaluation of tender bids (GbCF 3.4.7)<br>• Understand all the methods of raising awareness and educating patients<br><br>**SKILLS:**<br>• Exhibit leadership, management and governance in handling SF medical products issues<br>• Demonstrate effective communication and interpersonal skills<br>• Demonstrate critical and innovative thinking and practice<br>• Implement a system for documentation and record keeping<br>• Prepare pharmaceutical medicines (e.g., extemporaneous, cytotoxic medicines), determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.) (GbCF 2.2.1)<br>• Compound under the good manufacturing practice for pharmaceutical (GMP) medicines (GbCF) 2.2.2<br>• Demonstrate responsible counselling to patients (not causing mistrust in medicines)<br><br>**ATTITUDES:**<br>• Appreciate critical ethical, moral and professional value judgement principles<br>• Demonstrate social responsibility with regard to the SF medical products problem<br>• Avoid and discourage participation in informal medicines markets or unauthorised internet channels<br>• Be a role model in safe procurement<br>• Respect professional ethics |

| Learning outcome | Syllabus outline | Competency framework — competencies acquired through knowledge, skills and attitudes |
|---|---|---|
| | • International Conference of French-speaking Pharmacists — international association which condemned SF medicines through initiatives in 2006, 2011 and 2016<br>• International Institute of Research Against Counterfeit Medicine — launched campaigns to educate the public about SF medical products<br>• Alliance for Safe Online Pharmacies — developed a toolkit for pharmacists and other healthcare providers to educate patients about the risk of SF medical products<br>• The Partnership for Safe Medicines — developed safemedicines.org, a website which contains information about SF medical products for patients and healthcare professionals<br>• Rx360 — an international pharmaceutical supply chain consortium designed to achieve consistent supply chain standards worldwide<br>• WHO Member State Mechanism — a group established in 2012 to address the issue of SF medical products, providing communication frameworks for spreading SF medical product awareness<br><br>**C.4 — Role of pharmacists in the education of patients**<br><br>- Pharmacists can play a crucial role in educating patients on SF medical products by:<br>• Monitoring product alerts<br>• Providing opportunistic counselling on risks of obtaining medicines from unauthorised sources<br>• Applying the right of substitution where it is allowed<br>• Promptly reporting adulterated or counterfeited medicines to appropriate regulatory agencies and suppliers | |
| Module D<br><br>Detect SF medical products | **D.1 — Detection strategies**:<br><br>Product inspection:<br><br>- Visual inspection<br>• Analysing a product for differences from the usual product, including improper packaging, labelling, dose description, security features, incorrect language or missing dosage and strength information<br>- Physical inspection<br>• Evaluating a product's disintegration and dissolution performance, refractive index, or physical characteristics under a microscope<br>• Includes information provided by patients, such as changes in taste, colour, or medical response<br>- Chemical inspection<br>• Examining a product's properties via spectrometry, chromatography and wet chemistry<br>• Provides the most direct supporting evidence in favour of or against a product's quality<br>• Utilises spectroscopy, chromatography and colorimetry for most product analysis, with Raman spectroscopy being reserved for biological products<br>• Laboratory analysis is used when visual inspection is insufficient and involves field screening, quality assurance laboratory analysis and forensic laboratory analysis<br><br>Regulatory actions: | **KNOWLEDGE:**<br>• Recognise the advantages and disadvantages of different lab tests in different scenarios<br>• State the components of quality control systems applicable to pharmaceuticals and health products supply chains<br>• Describe the steps and principles of physical inspection<br>• Describe the steps and principles of analytical inspection and laboratory testing<br>• Identify which steps are at risk of SF medical products introduction in all pharmaceutical establishments (manufacturer, importation, wholesaler, end-user) and how to carry out controls<br>• Ensures medicines are not counterfeit and meet quality standards (GbCF 4.5.5)<br><br>**SKILLS:**<br>• Integrate knowledge into delivering clinical care for patients and ensuring their safety<br>• Demonstrate critical and innovative thinking and practices to ensure quality pharmaceutical and health supplies<br>• Apply critical inquiry and scientific method in quality control of pharmaceuticals and health supplies<br>• Recognise SF medical products by visual and physical inspection |

| Learning outcome | Syllabus outline | Competency framework — competencies acquired through knowledge, skills and attitudes |
|---|---|---|
| | - Recalls — removal of a specific batch or batches of a medical product from the market in response to detected deficiencies in quality, safety or efficacy<br>• Separated into classes depending on the level of health hazard<br>• Separated into types to denote the extent it should be recalled<br>- Medicines approval system<br>• Establishes a process for applicants to submit technical documents demonstrating quality, safety and efficacy for medicines to be sold<br>• In Africa, the African medicines regulatory authorities are responsible for ensuring quality, safety and efficacy<br><br>Target medicines and risk analysis:<br><br>- Target medicines are often difficult to determine, so every product should be inspected<br>- Patients should be educated about possible sources of SF medical products and there should be proactive communication with team about product recalls<br>• Make distinctions between generics and SF medical products issues<br>• Suggest patients compare prices of medical products — unusually low prices suggest SF medicines<br>• Discuss the risks in utilising internet pharmacies or foreign distributors<br><br>**D.2 — Link to quality control**<br><br>- Quality control<br>• Procedures that protect the identity and purity of medicines, ensuring regulatory adherence and manufacturing and quality standards<br>• Quality control helps prevent substandard products from being produced during manufacturing<br>• The WHO Expert Committee on Specifications for Pharmaceutical Preparations (WHO ECSPP) — provides recommendations for quality assurance and endorses international guidelines that outline all aspects of quality assurance<br><br>**D.3 — Link to pharmacovigilance**<br><br>- Pharmacovigilance<br>• The science of SF detection and prevention used to promote understanding and improve patient care and public health<br>• Utilises statistics to identify trends and trace SF medical products to suppliers and manufacturers<br><br>**D.4 — Technology**<br><br>Detection tools and verification systems:<br><br>- Consumer level detection<br>• Consumers can utilise mPedigree, a free service in which patients text a code on the label to a toll-free hotline to verify if it is safe<br>- Healthcare field level detection | • Demonstrate knowledge of basic analytic chemistry testing methods, apply knowledge from analytical chemistry<br>• Use contemporary methods to detect SF medical products<br>• Ensure appropriate quality control tests are performed and managed appropriately (GbCF 4.5.4)<br>• Develop and implement standing operating procedures (GbCF 4.5.3)<br>• Understand the principles, the advantages and limits of Mini-Lab use in rural areas and demonstrate how to run a test<br>• Demonstrate the ability to reference prices of medicines<br>• Demonstrate effective communication and interpersonal skills<br>• Exhibit leadership, management and governance in handling SF medical products issues<br><br>**ATTITUDES:**<br>• Demonstrate social responsibility with regard to the SF medical products problem<br>• Display enthusiasm for team and collective action<br>• Appreciate critical ethical, moral and professional value judgement principles in ensuring quality medicines<br>• Pay attention to suspicious cases<br>• Keep up to date and demonstrate willingness to use the latest anti-counterfeiting technologies and tracking systems |

| Learning outcome | Syllabus outline | Competency framework — competencies acquired through knowledge, skills and attitudes |
|---|---|---|
| | • Healthcare workers can utilise RxAll, a portable spectrometer that analyses a medicine's spectral signature and determines its quality level. After analysis, it sends a quality report to a mobile app for review by the healthcare professional<br>- Pharmaceutical industry detection<br>• Pharmaceutical manufacturers have been moving towards blockchain technology, a growing list of records linked through codes.<br>• Blockchain technology includes timestamps and transaction data to enable more security in the pharmaceutical supply chain<br><br>Portable screening devices<br><br>- Utilise primarily three technologies to verify a product:<br>• Infrared and visible light reflection<br>• Liquid chromatography<br>• Mass spectroscopy<br>- Provide qualitative verification rather than quantitative verification<br>- Examples:<br>• NIR scanner — utilises infrared and near-infrared spectroscopy to verify a product<br>• Rapid diagnostic test — utilises lateral flow immunoassay to verify a product<br>• Paper analytical devices— utilise paper-based colorimetry to verify a product<br>• TruScan RM — utilises Raman spectroscopy to verify a product<br>• pharmaChK — utilises microfluids technology to verify a product<br>• CD3+ tool — utilises sample illumination at specific wavelengths to verify a product<br><br>WHO guidance on developing workable traceability regulations — governance for traceability systems and use of global standards for product identification, production identification, automatic identification and data capture<br><br>• Examples of data carriers<br>• Serialisation to allow the identification of each single package of this product and therefore enable traceability<br><br>Storage:<br><br>- Proper storage maintains quality products<br>- In order to assure quality throughout a product's lifetime, medicines should be routinely inspected while being stored | |
| **Module E**<br><br>Report SF medical products | **E.1 — Reporting to relevant authorities**<br><br>SF medical product reporting can occur in a variety of ways:<br><br>- Personal reporting<br>- Online report forms<br>- Mobile applications<br>- Hard copy report forms<br><br>SF medical product reporting can occur on two levels:<br><br>- National<br>- International | **KNOWLEDGE:**<br>• Attain strong understanding of established systems for accurately reporting SF medical products, complaints and safety issues<br>• Distinguish the different documentation for reporting SF medical products<br><br>**SKILLS:**<br>• Accurately report defective or substandard medicines to the appropriate authorities (GbCF 2.3.2)<br>• Demonstrate ability to construct a plan for management of complaints, recalls and safety issues during the lifecycle of a medicine |

| Learning outcome | Syllabus outline | Competency framework — competencies acquired through knowledge, skills and attitudes |
|---|---|---|
| | - WHO — Global surveillance and monitoring system for SF medical products<br><br>Medical product alerts<br><br>- Issued by WHO to warn countries about the existence of an SF medical product<br>- Reports must meet a set of criteria to issue a medical product alert:<br>• Is the report validated (i.e., laboratory analysis)?<br>• Is there a threat to public health?<br>• Is there a risk in other countries?<br>• Are there other reports about the product?<br>• Has the product been removed from the supply chain or is it still in circulation?<br><br>Medical device problems vs. adverse events<br><br>- A medical device problem is something that happens to an in vitro diagnostic whereas an adverse event is something that happens to a person<br>- Complaints should be sent to the manufacturer, the national regulatory authority and the WHO<br>- Medical device issues should be reported to rapidalert@who.int<br>- Risk stratification should occur to identify affected parties and the severity to which they could be impacted. There are three broad risk categories:<br>• Critical risks<br>• Associated risks<br>• Historical risks<br><br>If you or a patient is unaware of how to report an SF medical product or whom to report it to:<br><br>- Contact the Pharmaceutical Security Institute<br><br>**E.2 — Reporting up the supply chain**<br><br>Recalls<br><br>- A removal of a specific batch of a medical product from the market because of a concern in the quality, safety or efficacy<br>- Can occur for several reasons:<br>• Serious adverse reactions not included in the summary of product characteristics (SPC) of the medicine<br>• Unexpected frequency of adverse reactions stated in the SPC<br>• Incorrect labelling or formulation of the product<br>- Overseen by national drug authorities<br>- Manufacturers can also issue recalls<br>- Require a variety of information:<br>• Name<br>• Dosage form<br>• Strength<br>• Pack size<br>• Batch/lot number (anything to identify the recalled product)<br>• Name and address of the manufacturer<br>• Total quantity being recalled | • Demonstrate critical and innovative thinking and practices in responding to cases of SF<br>• Identify, devise and co-ordinate appropriate communications to relevant stakeholders on new SF medical products cases<br>• Implement, conduct and maintain a reporting system for incidents (GbCF 4.5.8)<br>• Exhibit leadership, management and governance in responding to SF medical products cases<br><br>**ATTITUDES:**<br>• Record all cases accurately and completely<br>• Appreciate critical ethical, moral and professional value judgement principles in responding to SF medical products cases<br>• Keep up to date with latest reporting requirements<br>• Display enthusiasm for team and collective action<br>• Be proactive<br>• Demonstrate social responsibility in responding to SF medical products<br>• Demonstrate willingness to communicate with, guide, inform and educate other co-workers |

| Learning outcome | Syllabus outline | Competency framework — competencies acquired through knowledge, skills and attitudes |
|---|---|---|
| | •The date of distribution<br>•List of customers who received the product<br>•Reason for the recall<br>•Suggested action to be taken and its urgency<br>•Indication of health risk and justification for its categorisation<br><br>**E.3 — Systematic sharing of data**<br><br>Data collection<br><br>- Sharing valuable medical product information allows identification of SF medical product trends and vulnerabilities to focus efforts<br>- Accurate data are difficult to obtain since many counterfeiters avoid criminal prosecution<br><br>**E.4. — Developing reporting systems**<br><br>New reporting systems around the world:<br><br>- The Yellow Card Scheme<br>•Programme in the United Kingdom for collecting data on suspected safety concerns of medical product, including SF medical products<br>•Established by the Medicines and Healthcare products Regulatory Agency<br>•Allows reporting from both healthcare providers and patients<br><br>- MedWatch programme<br>•Programme in the United States of America for monitoring medical product safety<br>•Established by the Food and Drug Administration<br>•Allows reporting from both healthcare providers and patients<br><br>- Med Safety mobile application<br>•Easy-to-use smartphone application that allows providers and patients to report adverse effects and access medicine safety information | |
| **Module F**<br><br>Intervene with advice for patients exposed to SF medical products, | **F.1 — How to intervene in different situations: consuming SF medical products**<br><br>- SF medical products can present in the following ways:<br>•Correct drug, correct ingredients<br>•Wrong ingredients, but therapeutically active<br>•Wrong quantity of ingredients<br>•No active ingredients<br>•Toxic ingredients<br><br>- The role of the pharmacist:<br>•Analyse and address allergies the patient may have to the SF product<br>•Assess the severity of harm caused by the SF product | **KNOWLEDGE:**<br>• Recognise the effects of exposure to SF medical products and their management<br>• Apply first aid and act upon arranging follow-up care (GbCF 2.6.1)<br>• Appropriately refer (GbCF 2.6.1)<br>• Assess and diagnose based on objective and subjective measures (GbCF 2.6.1)<br>• Discuss and agree with patients the appropriate use of medicines, taking into account patients' preferences (GbCF 2.6.1)<br>• Document any intervention (e.g., document allergies, medicines and food, in patient medicines history) (GbCF 2.6.1) |

| Learning outcome | Syllabus outline | Competency framework — competencies acquired through knowledge, skills and attitudes |
|---|---|---|
| informing others etc. | • Evaluate the impact of the SF product on the patient's co-morbid conditions<br><br>**F.2 — Effects on the patient**:<br><br>Consequences of using SF medical products:<br><br>- Little or no therapeutic effect<br><br>- Harm<br>• Liver problems (hepatitis, cirrhosis)<br>• Renal damage<br>• Cardiac insufficiency<br>• Mental disorders and cognitive disabilities<br>• Respiratory complications (exacerbation of asthma or emphysema)<br>• Gastrointestinal tract issues (ulcers, intoxication)<br>• Local or generalised infections due to lack of sterility<br><br>- Therapeutic failures<br>• Doctor misdiagnosis or misinterpretation of therapeutic effect leads to changes in treatment, increased costs and potential for patient harm<br>• Emergence of antimicrobial drug resistance<br>• Death<br><br>The role of the pharmacist:<br><br>- Recognise the signs and symptoms related to SF exposure<br>- Provide patient education about their medicines and medical conditions<br>- Provide first aid if needed<br>- Refer the patient to a primary care provider after SF exposure<br>- Document the patient's reaction to the SF medical product<br><br>**F.3 — How to proceed with patients in SF situations**<br><br>Patient education:<br><br>- Show patients how to identify SF medicines<br>- Discuss the warning signs of unregulated medicine sources<br>• Websites that do not have an address or landline telephone<br>• Suspiciously low-priced medicines<br>• Sources that sell prescription medicines without a prescription<br>- Describe methods of communication should the patient be suspicious of their medicine<br><br>The role of the healthcare provider:<br><br>- Discontinue or modify treatment depending on the risks of SF medicine exposure vs. treatment disruption<br>- Incorporate a patient-centred approach to medical care | • Obtain, reconcile, review, maintain and update relevant patient medication and diseases history (GbCF 2.6.1)<br><br>**SKILLS:**<br>• Demonstrate clinical judgement, recognise affected patients and escalate management appropriately<br>• Exhibit clinical skills and patient care in managing cases of exposure to SF medical products<br>• Demonstrate critical inquiry and scientific/evidence-based method in managing patients exposed to SF medical products<br>• Effectively communicate with patients<br>• Demonstrate necessary innovativeness and critical thought in managing exposure to SF medical products<br>• Identify, devise and co-ordinate appropriate communications to relevant stakeholders (colleagues, public and authorities) on cases of exposure to SF medical products<br><br>**ATTITUDES:**<br>• Show empathy and respect for patients<br>• Demonstrate professionalism<br>• Demonstrate moral and ethical value judgement<br>• Demonstrate social responsibility<br>• Demonstrate willingness to communicate with, guide, inform and educate other co-workers |

| Learning outcome | Syllabus outline | Competency framework — competencies acquired through knowledge, skills and attitudes |
|---|---|---|
| | • Respect for patients' values, preferences and expressed needs<br>• Coordination and integration of care<br>• Educate patients on SF medicines<br>• Provide support for patients who have adverse reactions<br>• Emotional support and alleviation of fear and anxiety<br>• Involvement of family and friends<br>• Continuity and transition of care<br>• Discuss barriers to care<br><br>**F.4 — Communication of information**<br><br>Maintaining communication is vital to minimizing the impact of SF medicines:<br><br>- Communicate recalls pro-actively to the public<br>- Educate healthcare providers about SF product identification<br>- Reach out to regulators and governing bodies about the discovery of SF medicines and investigations of SF medicine sources | |

# 6.2 Appendix 2: Modular practical exercises

## 6.2.1 An exercise to understand the principles of the integrity of the supply chain and products most at risk (Module B)

Selected skills from and/or linked to the competency framework:
- Perform risk analysis of SF medical products problem in your country
- Lead critical inquiry and apply scientific method in managing SF medical products
- Demonstrate effective communication and interpersonal skills
- Demonstrate critical and innovative thinking and practice
- Exhibit leadership, management and governance in handling SF medical products issues

Selected attitudes from and/or linked to the competency framework:
- Perception of the scale and form of SF medical products
- Perform lifelong self-directed learning to keep up to date with most valid and factual information about the incidents

### Practical exercise

*1. Identify and analyse those products that are most at risk of being substandard or falsified in your country.*
*(a) How could you identify products that are likely to be substandard or falsified?*
*(b) What information sources are available to you to identify SF medical products?*
*(c) What are the characteristics of medical products at risk?*

*Deliver a short presentation to the group listing the SF medical products you consider to be most at risk. Describe the steps you took to identify these at-risk products (including the information sources you used) and list what their characteristics are.*

### Risk analysis

The estimation of the risk associated with the identified hazards.
The systematic use of available information to identify and assess the risk:

1. How bad is the situation?
2. How often does it happen? Has it happened before?
3. What can go wrong?
4. Do I need to act?

### Learning Points

*(1a) Undertake a desktop analysis of the information sources.*

*Consider the risks that lead to the production of SF medical products.*

Shortage of medicines, gives incentives to buy from unregulated suppliers. Both patients and physicians may respond to these shortages by exploring outside the regulated supply chain to secure the medicines they need.

Unmet demand for premium products, gives incentive to buy from unregulated suppliers. Marketing and prescribing practices that create unmet demand for higher-margin products usually raise costs to patients. Patients who want, but cannot afford, a premium product that is not covered by their

insurance may again look beyond the regulated supply chain, sourcing the product online or in informal markets.

In an attempt to protect profit margins, commercial strategies combine to create unmet needs and demand, and to drive people to sellers outside the regulated supply chain. This creates a niche in the market for criminals who wish to sell falsified products.

Factors that contribute to the proliferation of substandard and falsified medicines include both the unintentional and deliberate neglect of good manufacturing practices. This stimulates the circulation of substandard drugs, while falsification of medicines has its roots in crime and corruption. Both types of products circulate because of the unpredictable supply and constant demand for medicines and insufficiencies in the regulatory system. This illegal operation thrives in places where regulation is weak, technical capacity is lacking and the risk of detection is low. A poor understanding of the issue among health professionals and the public contributes to the problem.

Substandard and falsified medical products are most likely to be circulating in supply chains when:

- Access to affordable, quality, safe and effective medicines is limited;
- Standards of governance are low, from a lack of ethical practices in health care providers and medicine outlets, through to corruption in both the public and private sectors; and
- The tools and technical capacity to ensure good practices in manufacturing, quality control and distribution are limited.

Substandard and falsified medical products reach patients when the tools and technical capacity to enforce quality standards in manufacturing and the supply chain are limited. Technical limitations also affect falsified products, but their circulation in the market is further promoted by corruption and other shortcomings of regulation and governance, including unethical practices by wholesalers, distributors, retailers and healthcare workers. However, a high proportion of cases so far reported to the WHO occur where these problems overlap with constrained access.

- Constrained access to affordable, safe and quality medical products
    - Affordability
    - Availability
    - Acceptability
- Lack of good governance
    - Overstretched regulatory frameworks
    - Transparency and accountability
- Weak technical capacity and tools
    - Following standard procedures: the first step to quality products

*(1b) What are the characteristics of medical products at risk?*

Substandard production and falsification affect all types of medical products.

Common classes of SF medical products include antimalarials, antibiotics, vaccines, HIV treatments, medicines affecting the central nervous system, cardiovascular medicines, antidiabetics and anticancer medicines.

In developed countries, mostly life-style medicines such as slimming pills, treatment for impotence (sildenafil), hormones or steroids can be substandard or falsified.

In developing countries, however, life-saving medicines such as antibiotics and antimalarials are substandard or falsified. Life-saving medicines are nowadays the fastest growing category of falsified medicines. Medical devices such as contact lenses, condoms, syringes, surgical instruments and wheelchairs are also affected.

SF medicines can be both prescription and over-the counter medicines; moreover, they can also be brand-name or generics. Both very expensive and inexpensive medical products can be substandard of falsified (also medicines with high level of prescribing or in high-demand, off-label used drugs and

parenterals in developing countries are prone to being falsified). Medical products of which there is a shortage are also good candidates for counterfeiting.

Stress the importance of WHO product alerts.

### Summary — why is risk analysis of SF medical products important?

Gathering as much information about SF medical products as possible is important, in order to validate the information. An analysis should seek to identify the medical products most at risk, vulnerabilities in supply chains and weaknesses in capacity and health systems.

Data analysis equips policy makers and regulators with detailed information identifying emerging trends quickly, better informing post market surveillance and more focused investment for capacity building and regulatory strengthening.

A system of risk analysis facilitates a more accurate assessment of the scope, scale and socio-economic harm caused by SF medical products and contributes to combating SF medical products.

### Information sources (see also Module B slides):

- World Health Organization. Report on the WHO global surveillance and monitoring system for substandard and falsified medical products. WHO. 2017. Available at: https://www.who.int/medicines/regulation/ssffc/publications/GSMSreport_EN.pdf?ua=1
- Gillian J. Buckley and Lawrence O. Gostin, Editors; Committee on Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products; Board on Global Health. Institute of Medicine. 2013. Available at: https://www.ncbi.nlm.nih.gov/books/NBK202531/#!po=1.04167
- World Health Organization. WHO official website: https://www.who.int/•WHO
- World Health Organization. Full list of WHO medical product alerts: https://www.who.int/medicines/publications/drugalerts/en/
- World Health Organization. WHO information about SF medical products: https://www.who.int/medicines/regulation/ssffc/en/
- World Health Organization. A study on the public health and socioeconomic impact of substandard and falsified medical products. WHO. 2017: https://www.who.int/medicines/regulation/ssffc/publications/SE-Study_EN_web.pdf?ua=1
- European Medicines Agency. EMA official website: https://www.ema.europa.eu/en
- European Medicines Agency. EMA Falsified medicines: overview: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/falsified-medicines-overview
- Food and Drug Administration Agency. FDA official website: https://www.fda.gov/home
- Food and Drug Administration Agency. FDA Counterfeit medicine: https://www.fda.gov/drugs/buying-using-medicine-safely/counterfeit-medicine
- Pharmaceutical Security Institute website: https://www.psi-inc.org/
- International Institute of Research Against Counterfeit Medicines: http://www.iracm.com/en/
- International Federation of Pharmaceutical Manufacturers & Associations, Falsified medicines: https://www.ifpma.org/topics/falsified-medicines/
- International Federation of Pharmaceutical Manufacturers & Associations, Fight the Fakes: https://www.ifpma.org/partners-2/1236/
- Interpol. International crime operations: https://www.interpol.int/en/Crimes/Illicit-goods/Pharmaceutical-crime-operations

## 6.2.2 An exercise to be able to procure and compound safely (Module C)

Selected skills from and/or linked to the competency framework:

- Exhibit leadership, management and governance in handling SF medical products issues
- Demonstrate effective communication and interpersonal skills
- Demonstrate critical and innovative thinking and practice
- Implement a system for documentation and record keeping
- Prepare pharmaceutical medicine (e.g., extemporaneous, cytotoxic medicines), determine the requirements for preparation (calculations, appropriate formulation, procedures, raw materials, equipment etc.) (GbCF 2.2.1)
- Compound under the good manufacturing practice for pharmaceutical (GMP) medicines (GbCF) 2.2.2
- Demonstrate responsible counselling to patients (not causing mistrust in medicines)

Selected attitudes from and/or linked to the competency framework:

- Appreciate critical ethical, moral and professional value judgement principles
- Demonstrate social responsibility with regards to the SF medical products problem
- Avoid and discourage participation in informal medicines markets or unauthorised internet channels
- Be a role model in safe procurement
- Respect professional ethics

## Practical exercise

*(1a) List the main safety issues related to the pharmaceutical supply chain when SF medical products become part of it.*
*(1b) Describe the challenges in securing a safe pharmaceutical supply chain.*
*(1c) Discuss how these challenges can be overcome and SF medical products prevented from entering the supply chain.*

*Illustrate and present the above in the form of a diagram/picture/infographic that includes steps in the supply chain.*

## Learning points

*(1a) Main issues related to the pharmaceutical supply chain:*

I. Issues related to SF medical products
II. Adverse reactions of patients to the medicines
III. Number of issues are increasing due to increasing complexities of supply chain operations
IV. Manufacturing issues like mixing incorrect input raw materials, or cross contamination due to manufacturing more than one drug in the same facility, or improper labelling of the final product
V. Retailer's issues including improper temperature controls and handling
VI. Transportation issues caused by mishandling, improper temperature controls and the use of improper shipping modes
VII. Storing and warehousing issues such as using improper temperature controls, improper handling in the warehouse and mixing products with raw materials
VIII. Raw material suppliers' issues such as improperly prepared raw material, raw material with high impurity levels and mislabelling of raw material shipments

*(1b) Challenges in the pharmaceutical supply chain:*

The key stakeholders in the supply chain include multiple government agencies, hospitals, clinics, pharmaceutical manufacturers and distributors, pharmacies, research organisations, national regulatory authorities etc. Numerous other organisations, e.g., insurance companies, may further increase complexity. Many pharmaceutical supply chains have grown in an uncontrolled fashion

Challenges in the pharmaceutical supply chain include:

- Order management
- Warehouse management
- Shortage avoidance
- Lack of coordination
- Inventory management
- Absent demand information
- Human resource dependency
- Expiration
- Temperature control
- Shipment visibility

*(1c) Prevention of SF medical products entering the supply chain*

There are three steps to go through to properly qualify your suppliers and thereby protect the supply chain (see Figure 1).

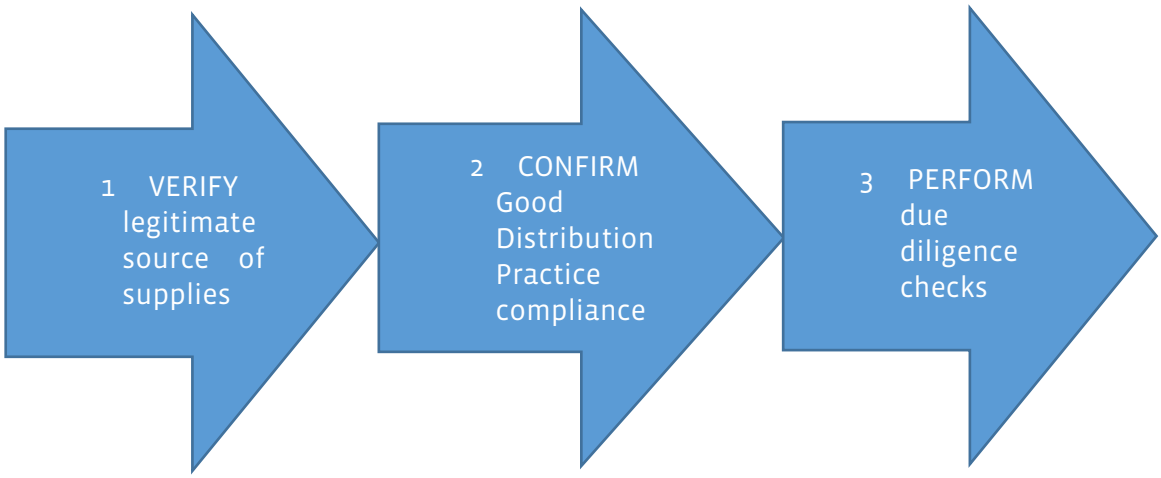



Figure 1. Steps for Prevention of SF medical products entering the supply chain

**Step 1**

The first step is to verify that supplies of medicinal products only come from legitimate businesses that are in possession of a wholesale distribution authorisation, or that are in possession of a manufacturing authorisation which covers the product in question.

Copies of licences can be requested from suppliers. In addition, details of a licence of a supplier can usually be viewed via the national regulatory authority's website. It is important that these registers are updated regularly, although they must not be relied on as a sole means of qualifying suppliers' authority to supply. One practical way to prove legitimacy of suppliers is obtaining a printed copy of the appropriate pages, signed and dated as confirmation the checks were made, when and by whom.

For supplies obtained from wholesalers and manufacturers based in other countries the same checks should be made on relevant websites and via licences that have been translated and authenticated by a notary. Some countries also have their own registers, and these can also be referenced to support qualification.

**Step 2**

The second step requires that wholesalers confirm that they comply with good distribution practices. To ascertain good distribution practice (GDP) compliance, the GDP certificate of the wholesaler should be viewed on the relevant website. The certificate should be in date, and the certificate expiry should be recorded.

Check for conditioning statements to GDP certificates for new applicants and those companies where the inspection outcome indicated a more frequent inspection schedule is required, limiting certificate expiry to a specified period.

If there is no GDP certificate available then other evidence of GDP compliance by the wholesalers should be obtained, such as a copy of their latest inspection close out letter confirming GDP compliance.

### Step 3

The third step is the timely rechecking of the information obtained and due diligence.

Wholesalers must be aware of issues that could affect their suppliers' continued authority to supply. A procedure that ensures there are regular documented check of lists of suspended licence holders and regular checks on appropriate websites for issued GMP and GDP statements of non-compliance must be in place. There should be at least an annual full revalidation of the information held on suppliers.

When entering a new contract with new suppliers, the wholesale distributor should carry out due diligence checks in order to assess their suitability, competence and reliability. Considerations include:

- Checking the financial status of the supplier, length of trading, credit history etc;
- Checking audit of the supplier, or results of a visit;
- Identifying where is stock coming from and if a new product is being offered;
- Checking if the product is being offered in very high quantities or volumes or if the price offered is much lower than usual;
- Checking transparency of the supply chain; and
- Checking methods of transportation.

Due diligence checks should be implemented and documented when dealing with a company or transaction that is outside an established trading pattern.

Criminals actively look for weak points in the supply chain so they can profit. Criminals may illegally copy the licence and address details of a legitimate company but set up a fake website and bank account that is similar to the real operation. Typically, this bogus company will offer some enticing stock and send information using genuine company details but from a different email account, possibly substituting ".com" for ".net", or from a closely related website name. The bank account information will be for the bogus company. Caution is needed if the supplier advises that its bank details have changed.

Shortages of medical products should always be considered warning signs. Health authorities and others should make regulators aware so that they can then increase their alertness around those products, working with customs officials at ports and through surveillance of the supply chain.

There needs to be clear and regular communication with civil society groups, health care professional organisations, the pharmaceutical industry and organisations within the supply chain, specifically focusing on substandard and falsified medical products.

Also needed 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.

A track and trace system with an authentication process should be 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.

Considerations include:

- Conducting independent research into the company — review of official sources of information, such as national records;
- Ensuring details provided by an organisation match online details;
- Calling phone numbers or test contact details;
- Validating bank details;
- Ensuring internal training programmes include individuals/departments which may be approached outside your direct knowledge, such as finance, and equip staff with mechanisms to report changes to supplier or customer details of which you may not be aware;
- Ensuring processes and assessments are in place to confidently establish the identity of a prospective supplier;
- Being aware that unexpected types, volumes and prices of products being offered and unusual availability can be a potential risk;
- Understanding that risk management processes minimise the prospect of falsified medicines entering the supply chain;
- When re-qualifying suppliers, considering if any significant changes in directorship or ownership have occurred;
- Ensuring staff and management can be confident that replies are only sent to approved and valid e-mail addresses;
- Being aware that integrating reporting mechanisms from goods in processes introduces deviations into the quality management system; and
- Reviewing new contact details

#### 6.2.2.1 Safe procurement of medicines in community settings

Procurement should provide a medicine which is of an appropriate quality and which is safe in use at all stages of its lifetime, i.e., prescribing, dispensing, preparation, administration and disposal. Capabilities of the supply chain should be assessed to ensure products are genuine, stored correctly and available when required.

*Exercise*

*You are a pharmacist working in a community pharmacy, describe the steps you would take to ensure that procurement practice is safe?*
*What documentation would be necessary?*

The steps of correct procurement are:

***1. During procurement, the organisation should be able to determine the need for a product. Some industries have standards they use to help determine product specifications.***

- In the pharmaceutical supply chain, medicines for procurement should be based on the national essential drugs list. You can also consult "The use of essential drugs, WHO Technical Report Series No. 895, Geneva 2000".
- A reliable system for quantification of the drug needs is required to avoid wastage or scarcity.
- Most small countries usually base their requirements on past consumption.
- It is also possible to compare reports of drug consumptions versus the stock documentation to identify the medicines in scarcity.

***2. Source determination/vendor selection***

- Procurement should be from suppliers registered, evaluated and qualified by your country's regulatory authorities. Specify in the supplier contract the standard specifications of the pharmaceutical products with respect to quality, storage conditions and the type or mode of delivery. Have a limited range of suppliers to procure from to avoid infiltration of SF.

- Ensure there is no conflict of interest, open and fair competition attracts good suppliers. A lack of transparency might cause suppliers to disengage and not take part in future tenders, which will minimise the numbers of bidders and reduce competition. Written procedures for all procurement actions should be established and followed. Also, the information about the tender process and the results should be made public to the extent permitted by law.

*3. Adequate price check and terms*

- The buyer (wholesaler/hospital/pharmacy etc.) will investigate all relevant information to determine the best price and terms for the product. The aim is to provide quality drugs in the right quantities at the lowest possible cost when needed.
- After thoroughly evaluating the offers from suppliers, a special committee or tender board usually awards the tenders. It is important that a pharmacist or a person with technical knowledge of pharmaceutical products and its manufacture would be a member of the tender board.

*4. Purchase order*

- The purchase order is used to buy materials from a seller. It defines the price, specifications and terms and conditions of the product or service and any additional obligations. When it comes to medicines, information like dosage form or strength is also important.

*5. Purchasing order delivered*

- The purchase order must be delivered by fax, mail, courier, or email or other electronic means.
- The recipient/provider of the medicines then acknowledges receipt of the purchase order.

*6. Receipt and inspection of purchases*

- After receiving the order of medical products, the buyer should compare the medicines with the supplier's receipt and the purchase order.

*7. Invoice approval and payment*

- The supplier of medical products should make a request for payment in writing, accompanied by an invoice describing the medical products delivered and services provided, and by the shipping documents. Payments should be made promptly. The agreement on payment procedure and conditions should be clearly stated in the contract and even in the bids from potential suppliers while procurement takes place.

*8. Record maintenance*

- In the case of audits, maintain proper records. These include purchase records to verify any tax information and purchase orders. The supplier's performance should be recorded as well, with emphasis on timely and correct delivery, quality of medicines and their shelf life after delivery. These records might provide a guide in the future procurement and purchases as well.
- Monitor and store procurement documentation provided by suppliers or other parties to enable tracking products that might be SF.

#### 6.2.2.2 Safe procurement of medicines in hospital setting

*Exercise: You are a pharmacist working in a hospital, what are the differences and similarities with safe procurement in a community pharmacy?*

The operational steps are similar to the community settings. It also includes more strategic procurement.

*1. Source determination/vendor selection — It is necessary to determine where or from whom to obtain the product.*
The company/wholesaler/hospital etc may have an approved vendor list. Procurement methods include tenders, competitive negotiation or direct procurement. Selection of reliable suppliers of quality medical products is essential. New suppliers should be alerted on product quality issues when procuring, in addition to existing suppliers.

In hospital pharmacies, adopting pre-qualifying and post-qualifying systems for suppliers reduces the infiltration of SF medical products. Specification of storage conditions of medicines and their proposed quality standard should be known to suppliers during procurement.

Pharmaceutical tendering involves different stakeholders and steps in the process are regulated by national authorities. This inevitably means a variety of solutions in different countries. These processes are also guided by publications of other international organisations such as the WHO and the OECD (Organisation for Economic Co-operation Development).

The procurement process should be part of the hospital quality system. It should be assessed regularly, and quality improvement actions taken to improve the outcomes of clinical effectiveness, cost effectiveness and patient safety. A judicious tendering procedure has the potential to achieve substantial cost savings depending on the purchasing power of the organisation and the market diversity for the products involved. Negotiations driven mainly by costs may achieve short-term savings but there is a risk of medicines shortages and long-term price increases.

Manufacturing capacity may not meet potential need and if other suppliers drop out of the supply chain due to loss of tender this can cause weaknesses. Tendering should include impact assessment tools and continuous monitoring of supply chain vulnerability and sustainability.

## 2. Receipt of medicines
The "internal" supply chain should also be robust and fit for purpose, i.e., the arrangements ensure products are available for patients and are of the appropriate quality.

*Discussion — You have received a delivery of commercial products in your hospital pharmacy constituted of sterile components. What do you need to check before accepting the product?*

Sterile products are comprised of active and inactive ingredients, intermediate containers (e.g., a syringe used to transfer a medicine from one container to another), final containers, closures and seals. When sterile products are delivered, they should be transferred to their manufacturer-designated storage environment as soon as possible, especially temperature-sensitive products that can reach temperature equilibrium within minutes to hours depending on product, packaging and environmental conditions. Review delivery documents at the receiving area to ensure that the sterile products have not been subjected to any delays during shipment, which could result in exposure of the article to elevated temperatures or other undesirable conditions. Sterile products requiring specific handling or refrigerator temperature storage conditions, should have documented evidence provided by suppliers to show that the specified temperature range has been maintained throughout transportation. Staff receiving sterile commercial products should contact the product manufacturer to determine the significance of deviations from the specified temperature range during shipment.
When they are received in the pharmacy a standard operating procedure should specify the visual inspection of sterile products, sterile ready-to-use containers and devices (e.g., syringes and needles). All items must be free from defects, within the manufacturer's expiration dating, and appropriate for their intended use. Suitable records should be maintained to explain the reason for deviation from specified storage conditions and the resulting action taken. Defective medical products should be promptly reported to the national regulatory authorities.

## Information sources (see also Module B slides):

- Kapoor D, Vyas RB, Dadarwal D. An overview on pharmaceutical supply chain: A next step towards good manufacturing practice. 2018. Available at: https://lupinepublishers.com/drug-designing-journal/fulltext/an-overview-on-pharmaceutical-supply-chain-a-next-step-towards-good-manufacturing-practice.ID.000107.php
- World Health Organization. WHO Global surveillance and monitoring system for substandard and falsified medical products. WHO. 2017. Available at: https://www.who.int/medicines/regulation/ssffc/publications/GSMS_Report_layout.pdf?ua=1
- Brown P. What does risk qualification of suppliers mean to you? Risks to patients and your business. 2019. MHRA Inspectorate. Available at: https://mhrainspectorate.blog.gov.uk/2019/05/08/what-does-qualification-of-suppliers-mean-to-you-risks-to-patients-and-to-your-business/
- Orme T. Good Distribution Practice-Qualification of suppliers, a helpful reminder of the 3 steps needed to assure supply chain integrity. 2016. MHRA Inspectorate. Available at: https://mhrainspectorate.blog.gov.uk/2016/03/17/qualification-of-suppliers-a-helpful-reminder-of-the-3-steps-needed-to-assure-supply-chain-integrity/
- Moore T. Falsified Medicines and the supply chain. 2019. MHRA Inspectorate. Available at: https://mhrainspectorate.blog.gov.uk/2019/08/08/falsified-medicines-and-the-supply-chain/


### 6.2.3 An exercise to undertake a visual inspection of medicine (Module D)

Selected skills from and/or linked to the competency framework:

- Integrate knowledge gained from modules of SF medical products into delivering clinical care for patients and ensuring their safety
- Demonstrate critical and innovative thinking and practices to ensure quality pharmaceutical and health supplies
- Apply critical inquiry and scientific method in quality control of pharmaceuticals and health supplies
- Recognise SF medical products by visual and physical inspection
- Demonstrate knowledge of basic analytic chemistry testing methods, apply knowledge from analytical chemistry
- Use contemporary methods to detect SF medical products
- Ensure appropriate quality control tests are performed and managed appropriately
- Develop and implement standing operating procedures
- Understand the principles, the advantages and limits of Mini-Lab use in rural areas and demonstrate how to run a test
- Demonstrate the ability to reference prices of medicines
- Demonstrate effective communication and interpersonal skills
- Exhibit leadership, management and governance in handling SF medical products issues

Selected attitudes from and/or linked to the competency framework:

- Demonstrate social responsibility with regard to SF medical products problem
- Display enthusiasm for team and collective action
- Appreciate critical ethical, moral and professional value judgement principles in ensuring quality medicines
- Pay attention to suspicious cases
- Keep up to date and demonstrate willingness to use the latest anti-counterfeiting technologies and tracking systems

**Practical exercise**

The trainer should go through the visual inspection checklist and distribute it as a handout to pharmacy undergraduates.

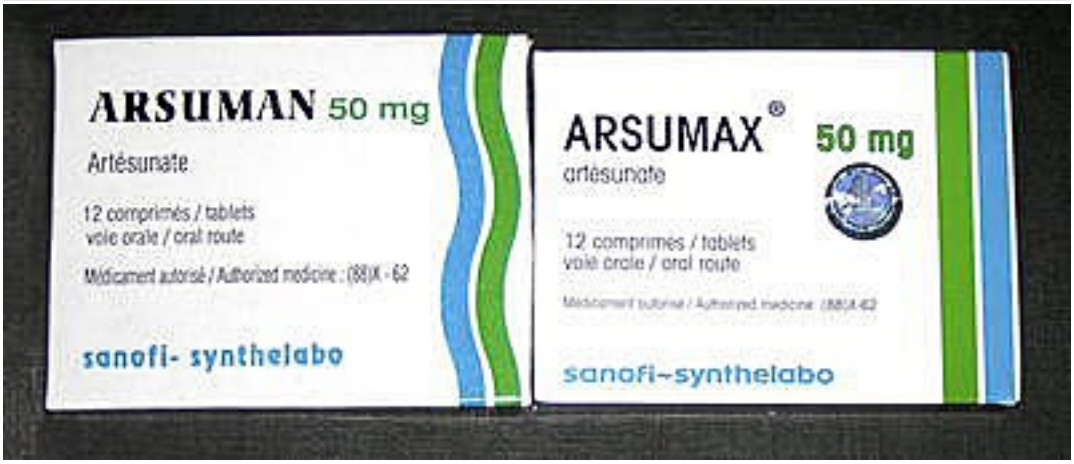
Use the visual inspection tool found in "Appendix 1: All you need to know about spurious medicines" in "A practical handbook for healthcare professionals in India. The World Health Professions Alliance. 2015" (https://www.fip.org/files/fip/WHPA_Handbook_India.pdf).

*1) Which of the medicines photographed below is legitimate? Give reasons.*


**Answer**

Left: Falsified Clomid tablets. Note the misspelling "Citrate de clomifère" instead of "Citrate de clomifène". Right: Falsified Azithromycin tablets. The indicated manufacturer "KIP Hamburg GmbH Germany" does not exist.

*2) Which of the examples below is likely to be genuine and which counterfeit?*



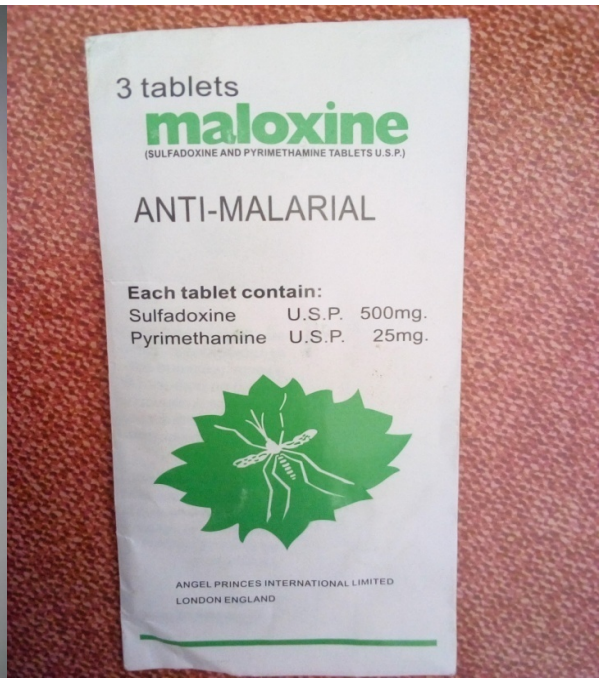

**Answer**

The box on the right is genuine (see hologram). The box on the left is fake (no hologram, no ® and incorrect spelling).

*3) Which of the tablets below is likely to be of concern and why?*

**Answer**
The tablets on the left are discoloured and degraded, and likely to be substandard.

*4) Which of the examples below is likely to be genuine and which counterfeit?*

**Answer**
The box on the left is a genuine Maloxine. The box on the right is falsified – see the logo with incorrect colours, as well as lack of information about the product.

### 6.2.4 An exercise to fill out the reporting form and report SF medical products (Module E)

Selected skills from and/or linked to the competency framework:

- Accurately report defective or substandard medicines to the appropriate authorities (GbCF 2.3.2)
- Demonstrate ability to construct a plan for management of complaints, recalls, safety issues during the lifecycle of a medicine
- Demonstrate critical and innovative thinking and practices in responding to cases of SF
- Identify, devise and coordinate appropriate communications to relevant stakeholders on new SF medical products cases
- Implement, conduct and maintain a reporting system for incidents (GbCF 4.5.8)
- Exhibit leadership, management and governance in responding to SF medical products cases

Selected attitudes from and/or linked to the competency framework:

- Record all cases accurately and completely
- Appreciate critical ethical, moral and professional value judgement principles in responding to SF medical products cases
- Keep up to date with latest reporting requirements
- Display enthusiasm for team and collective action
- Be proactive
- Demonstrate social responsibility in responding to SF medical products
- Demonstrate willingness to communicate with, guide, inform and educate other co-workers

**Practical exercise**

*1) Instruct undergraduates to complete a reporting form based on the Arsumax example from the module D exercise.*

**L**
The reporting form will depend on the one used by the national relevant authority.
National reporting is recommended in the first instance, but reports can also be made to the WHO and for the purposes of this exercise the adapted WHO form is used.

| **Reporting person** | | | |
|---|---|---|---|
| **Name** | | Organisation | |
| **Type of organisation** | | Country | |
| **Telephone number** | | Email | |
| **Discovery details** | | | |
| **Date discovered** | | Discovered by | |
| **Address or location where the suspect product was discovered (geographically)** | | Is the suspect product in distribution within your country? | |
| **Countries imported from** | | Is the suspect product available within the regulated | |

| | | | |
|---|---|---|---|
| | | or unregulated supply chain | |
| If available within the supply chain, at what level? | | Method of distribution to public | |
| If available via the internet, please record the website address. | | | |
| Suspect product details | | | |
| Suspect product name | | Type of product | |
| Is suspect product registered in reporting country | | Registration, product or marketing authorisation number shown on suspect product | |
| All APIs in product | | | |
| Main intended medical use | | Other uses | |
| Manufacturer | | Dosage form | |
| Container type | | Dosage strength | |
| Batch/lot number | | Expiry date | |
| Date of manufacture | | Packaging language | |
| Method of administration | | Quantity discovered | |
| Types | | Are photographs of the suspect product available? | |
| Product analysis | | | |
| Laboratory analysis undertaken | | Type of laboratory analysis undertaken | |
| Email address | | | |
| Results of analysis — packaging | | Results of analysis — dose | |
| Impact on public health | | | |
| Have adverse reactions been reported? | | Severity of adverse reactions | |
| Symptoms | | Estimated number of patients affected or at risk | |
| Communication | | | |
| Has any public statement been made? | | Date of public statement | |
| Has any product been withdrawn or recalled? | | Date of product recall | |

### 6.2.5 An exercise on counselling patients affected by SF (Module F)

Selected skills from and/or linked to the competency framework:

- Demonstrate clinical judgement, recognise affected patient and escalate management appropriately
- Exhibit clinical skills and patient care in managing cases of exposure to SF medical products
- Demonstrate critical inquiry and scientific/evidence-based method in managing patients exposed to SF medical products
- Effectively communicate with the patient
- Demonstrate necessary innovativeness and critical thought in managing exposure to SF medical products
- Identify, devise and coordinate appropriate communications to relevant stakeholders (colleagues, public and authorities) on cases of exposure to SF medical products

Selected attitudes from and/or linked to the competency framework:

- Show empathy and respect for patients
- Demonstrate professionalism
- Demonstrate moral and ethical value judgement
- Demonstrate social responsibility
- Demonstrate willingness to communicate with, guide, inform and educate other co-workers

## Exercise

*1a) Case study 1*

*JM is a 46-year-old male that has just arrived in your pharmacy seeking advice. He reports that one week ago, he was injured in a construction accident. An infection developed in one of JM's wounds and he was prescribed an antibiotic to treat it. Today in your pharmacy, JM admits that he did not get his antibiotic prescription dispensed at your pharmacy because he needed to save money while he is not able to work. Instead, he obtained the antibiotic medicine from an online source that had the medicine he needed at a "much cheaper price". After receiving his internet-ordered medicine, he has been taking it as directed, but he is now presenting with generalised weakness, a fever and the development of a rash.*

***What medical issue(s) could JM be experiencing?***
It is possible JM is experiencing increased side effects and/or a lack of efficacy in managing the infection in his wounds. It could be that there is an increase in the number of infections and the lack of effective treatment could signal the development of resistance due to the use of a SF medical product.

***What does the patient's medical history say about allergies?***
Could the patient's current condition be an allergic reaction?

***What other information is needed to fully analyse the case?***
What additional questions need to be asked of the patient and other healthcare professionals?

***What parts of the case are indicative of JM having potentially received a SF medicine?***
He obtained the antibiotic medicine from an online source and at a much cheaper price than usual.

***If JM has received a SF medicine, what is the next step in treatment?***
He needs to be referred for a reassessment of his wounds and an evaluation of the subsequent symptoms that may have resulted from receiving a SF medicine.

***What considerations in treatment need to be accounted for now that JM may have received a SF antibiotic?***
Whether the current treatment will still be effective is questionable. He should have his wounds swabbed and sent for sensitivity testing.

*Is resistance more of a concern now?*
Yes — if the SF antibiotic was inactive or subtherapeutic, resistance is likely. Once sensitivities of the infecting organisms to antibiotics are identified, the correct antibiotic can be selected. JM may require intravenous antibiotics.

*What reporting and documentation procedures need to occur?*
There should be full documentation of events in the patient's health record. If possible, send the suspected SF antibiotic to a lab for analysis. Complete a report for the national medicines' regulatory authority.

*How can a situation like this be prevented in the future?*
Discuss the S.A.F.E. D.R.U.G Checklist with JM.

**Exercise**

*(1b) Case study 2*

*YW is a 24-year-old female who is returning to the HIV adherence clinic today for her three-month HIV monitoring appointment. YW has been stable on her medication and her viral load has been undetectable throughout the course of treatment. In accordance with your clinic's adherence policies, YW brought her medicines with her to the clinic to show that she has been taking them properly and consistently. On inspecting the medicines, you realise that there are some subtle differences in the markings on one of the antiretroviral therapy products. After referencing a medicine standards resource, you confirm that the product is not genuine, and appears to be a very good counterfeit product.*

*YM has been receiving a SF medication for up to three months, and it appears to still be effective at controlling her disease, so should it still be discontinued?*
Evaluate the risks of posed by the spurious medicines versus treatment disruption.
The healthcare professional will have to decide whether the risk of potentially harmful substances in the spurious medicine outweighs the risk posed by interrupting the patient's treatment regimen. This consideration is of paramount concern in medical conditions where interruption of therapy is exceedingly detrimental.

*What follow-up questions can you ask YM to find out more information about the SF medicine?*
Where was the medicine obtained?
How long have you been taking the medicine?
When was the medicine purchased?
Do you have any of the original packaging that the medicine came in?

*As a pharmacist, should you report the discovery of the SF medicine?*
Yes, to the national medicines' regulatory authority.

*This SF medicine was used to treat HIV. What sort of dangers does a community face when medicines such as these are being used as therapy by chronically ill, contagious patients?*
There is a risk with sub-therapeutic treatment that viral loads increase, and this makes HIV easier to pass on with the result that infection rates may rise.

# 6.3 Appendix 3: Train the trainer delegate sign-up form

**PRE-TRAIN THE TRAINER COURSE DELEGATE INFORMATION**
**Training trainers and educators: Substandard and falsified medical products**

Name:
Date(s) attending:

In order for us to be able to sustain and enhance the quality of the programme, we would appreciate it if you could please answer the following:

Briefly explain your current role/position in relation to education and training of SF medical products.

Please provide details of any recent informal or formal education you have received in relation to education and training about SF medical products.

What do you hope to gain from attending the train the trainer programme?

To help us ensure that all delegates attending are able to participate fully, please let us know below about any requirements you may have, e.g., specific additional learning, communication, sensory or other requirements.

In case we cannot reach you, could you please provide contact details of either your department reception or a colleague who could pass on any messages.

Please return your completed form to: [add email].

# 6.4 Appendix 4: Train the trainer delegate evaluation form

**TRAIN THE TRAINER COURSE DELEGATE EVALUATION FORM**
**Training trainers and educators: Substandard and falsified medical products**

It is important that we continually check with you what you think about the course and if there are any changes we need to make. We would appreciate it if you could spend a few minutes at the end of the session today completing this form.

What I enjoyed about the session.

What are the most significant things I have learnt as a result of this experience?

Is there anything I might think differently about as a result of this experience?

s

Is there anything that could have been done differently?

Are there any general comments that I would like to make?

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