

A curriculum for addressing the risk of substandard and falsified medical products sold online

A handbook for educators

2024



Colophon

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Foreword

Substandard and falsified (SF) medical products are a global public health concern for the International Pharmaceutical Federation (FIP). The spread of SF medical products threatens patient safety, causes undesirable patient outcomes, results in a lack of public trust in our healthcare systems, disrupts economic advancement, and poses challenges to treat infections such as malaria and antimicrobial resistant diseases. SF medical products are often available in countries where there is poor manufacturing or limited numbers of medicines.

Although SF medical products cause major problems in the healthcare system around the world, there is a lack of awareness and knowledge about them. Educating healthcare professionals including pharmacists, students, and the public is of great importance to avoid the use of SF medical products. There are several educational examples for this issue, one of which includes the FIP online course on substandard and falsified medical products for pharmacy students, which was developed in 2021 and is available on the FIPx platform.

In recent years, patients and caregivers have increasingly used websites and social media to obtain medical products. Self-diagnosis and self-prescription have increased the use of illegal online drug sellers where SF medical products are sold. Identifying SF medical products is difficult for patients and healthcare professionals. Similarly, identifying legal online pharmacies can be challenging for patients and healthcare professionals alike. Gaps in knowledge and skills in undergraduate students remain, as most courses may not cover the online sale of SF medical products.

In this handbook, you will learn how FIP developed a new module on SF medical products sold online. You will also learn about regulatory examples from various countries regarding the online sales of medical products. This handbook also provides advocacy points for pharmacists who have a crucial role in ensuring public safety globally.



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Executive summary

The internet has increasingly become a tool for obtaining prescription, non-prescription, and illicit drugs via online sources. Illegal online drug sellers are a clear risk for substandard and falsified (SF) medical products and illegitimate drug supply chains. They can sell a wide spectrum of medications such as anti-infectives, causing antimicrobial resistance due to SF antimicrobials.

Pharmacists are among the most trusted healthcare professionals, serving as medication experts for patients and communities. With the risks of SF medical products obtained from illegal online drug sellers, pharmacists must have the necessary knowledge and skills to educate patients about reliable websites and avoid illegal online drug sellers. They must be able to identify SF medical products and illegal online drug sellers and counsel patients on obtaining appropriate medical products online.

Due to the high importance of illegal online drug sellers and SF medical products sold online, FIP developed five new modules to be embedded into existing SF medical product curricula. The modules were developed by FIP and reviewed by the FIP expert group to provide good quality training materials for educators.

This handbook aims to guide educators on the breadth, depth and risk of SF medical products sold online. Global examples of interventions to avoid SF medical products and regulate online pharmacies are also included. The materials of the new modules are available on the FIPX platform to be used by educators and trainers.

1. Introduction to the risk of SF medical products and the online pharmacy

The internet has become a tool for obtaining prescription, non-prescription, and illicit drugs via online pharmacies and websites.¹ With the advent of the internet and the rise of e-commerce, the use of online pharmacies has grown significantly worldwide.^{2,3} It is estimated that there are 30,000 to 35,000 active online pharmacies at any given time.^{4,5} However, not all of these online pharmacies or websites are legitimate and regulated.¹ More than 96% of online drug sellers are not operating in compliance with local regulations.^{4,5} The internet may be more likely to be misused or abused to sell unsafe and ineffective medications such as substandard and falsified (SF) medical products.

Over 50% of medications bought online from websites that did not disclose their physical address were discovered to be substandard or falsified.⁶ Consumers choose websites due to accessibility, potential cost savings and convenience. However, the number of reputable websites is significantly outnumbered by those that operate illegally.⁷

1.1 What is an online pharmacy?

An online pharmacy is defined as a company that sells medicines, including prescription-only medicines, over the internet and delivers them by mail.⁸ Briefly, an online pharmacy is a website offering to deliver, distribute, or dispense medication on the internet directly to consumers.^{9,10}

The first online pharmacy operated in the United States (US) in the late 1990s. It sold prescription only and non-prescription medications.^{9,11} In 2009, around 3000 websites were selling prescription medicines in the US.⁹ In 2011, the number of online pharmacies is growing continuously.^{9,11}

Illegal online drug sellers can be described as online-accessible outlets that are not:⁵

- Licensed by the state board of pharmacy in the state in which its patients are located and the state from which the pharmacy dispenses drugs;
- Dispensing medication pursuant to a valid prescription based on a proper physician-patient relationship; or,
- Selling only Food and Drug Administration (FDA)–approved medication, unless an approval exemption applies.

Illegal online drug sellers are thriving in a digital environment that provides benefits of anonymity, using rapid advancement of technology, providing insufficient international regulation, and causing clear risk factors for SF medical products and illegitimate drug supply chains.³ They can act against regulations and sell prescription medications without a valid prescription, adequate directions for safe use, or required warnings and with unclear safety and efficacy information.¹²

On the other hand, online pharmacies are more accessible to people with limited mobility and to people in remote areas.¹³ They save logistics costs for patients, enables them to place orders 24 hours a day, offer mailed delivery of medications, and enable comparison of prices and availability of medications.¹³ If they are well regulated and operated, online pharmacies can:¹³

- Promote interprofessional collaboration through telehealth services;
- Create a central repository of medical information for patients;
- Create increased ability to implement automated systems that will detect DDIs;
- Improve adherence to prescriptions through automatic periodic medication orders;
- Provide increased access, lower transaction and product costs, and anonymity; and,
- Reduce overhead costs for the pharmacy and remove the need to operate several pharmacy outlets.

1.2 Risks of online pharmacy and SF medical products sold online

There are many patient safety risks associated with illegal online drug sellers.¹⁴

- They can pose a risk of distribution of SF medical products, which may result in patient harm and suboptimal treatment, leading to an overall mistrust of medications, healthcare providers, and health systems.¹⁵
- They can cause misuse of personal health and financial information. Some criminal organisations collect personal financial and location data to process payments for the ordered products.¹⁵
- They can cause misuse or abuse of medications leading to emergency department (ED) visits. FDA warnings suggested that medications obtained over the internet can cause ED visits.¹
- They can interrupt medication therapy management by causing polypharmacy, drug-drug interactions, or duplication or omission of medications as it is very difficult for healthcare providers to verify patients' medication regimens to avoid such incidences.¹
- They can sell a wide spectrum of medications for infectious diseases, non-communicable diseases, controlled substances or drugs of abuse, and life-saving medicines.³ This may cause antimicrobial resistance, failure to antimicrobial therapy or addition to certain medications, which have more side effects.
- They operate by requiring the patient to complete an online questionnaire, which is then reviewed by a prescriber, forgoing any physical examination. This process may bypass a pharmacist's medication review for appropriateness of therapy, dosing, and drug interactions.¹
- They can cause inappropriate self-diagnosis or incomplete management of drug-related issues when there is no healthcare provider involved in the medication provision process.²

The risks highlight the great need for local and global regulations on operating online pharmacies.

1.3 Regulations and gaps for online pharmacies with the risk of selling SF medical products

According to a World Health Organization (WHO) survey, 66% of countries have no legislation that either explicitly allows or prohibits internet pharmacy operations.¹⁶ Medications are different from most items that can be sold online and can pose significant risks for patient safety. Therefore, policy makers and regulators must consider the safety of patients because the users of online pharmacies, whether legitimate sites or not, are purchasing medications used for both acute and chronic conditions, which may result medication harm.² Online selling of medication can also pose a threat to patients through the marketing of SF medical products.²

There are various interventions to regulate online pharmacies and their risk of selling SF medical products, from organisation level and country level. For example, the FDA shut down 1677 websites for selling SF medical products or for selling medications to consumers without appropriate safeguards in 2013.¹⁷ The Council of Europe's Medicrime Convention emphasised the risk of internet sales of medicines and considers them 'aggravating circumstances' when applying sanctions to offenses under the convention.¹⁸ FIP, as a long-term observer to the EDQM's Committee of Experts on Minimising the Public Health Risks posed by Falsified Medical Products and Related Crimes (CD-P-PH/CMED) has been vocal about this issue for the past two decades.

FIP's member organisations have been putting forward regulations to protect patients. For example, in Nigeria, all internet-based pharmaceutical services providers must be registered with the Pharmacist Council of Nigeria and must make the site user friendly and interactive so as to ensure proper consultancy services, educating patients, contacting patients regarding delays or other feedback, and reporting of adverse drug reactions by patients. In India, various laws govern online pharmacy and certification by the registered pharmacist must be obtained before delivery of drugs procured online.

In the European Union, pharmacies or retailers registered with their national authority to sell medicines online should display on their website the common EU [logo](#) for the online sale of medicines. The logo consists of the flag of the EU country where the pharmacy or retailer is registered and the words 'Click to verify if this website is operating legally'.¹⁹

In the USA, to improve safe and legitimate access to medicines, the National Association of Boards of Pharmacy (NABP) has established the (dot) .Pharmacy Verified Websites Program which provides pharmacists and consumers with an updated list of reputable online pharmacies.²⁰ The NABP's verification criteria include ensuring proper licensure, enforcing comprehensive policies, verifying prescription integrity, maintaining patient confidentiality, offering consultative services, and ensuring secure shipment and storage of medications.¹⁸ Organisations like the Royal Pharmaceutical Society (in Great Britain) are also working to help consumers verify the legitimacy of internet pharmacies. They introduced a logo which can be seen on the home page of participating online pharmacy web sites^{21,22} and they engage in awareness campaigns and strategic measures to combat the proliferation of illegal internet pharmacies. National authorities need to ensure stricter legislation and enforcement against these illegal operations.²¹

Educating the public about the dangers of purchasing medications online from unverified sources is also essential. As the closest healthcare professional, pharmacists must also be aware of the risk of illegal online drug sellers and obtaining SF medical products online. To educate pharmacists on these issues, the University of Utrecht School of Pharmacy developed a course on "internet medicines".²³ This course focuses on the task areas of quality assurance, product assurance and the following competences: knowledge and science, communication (learn to communicate with patients about the dangers of ordering medicines via the internet), professionalism (develop a professional attitude towards the quality policy in the pharmacy and be aware of your professional responsibility for patient safety) and social action (respond adequately in the event of a possible counterfeit product).²³

In conclusion, there is an increase in the use of the internet to obtain medications and medical products which poses risks in patient safety in many aspects. Healthcare professionals have limited knowledge about detecting illegal online drug sellers and SF medical products sold online. Selling medicines online is not well regulated globally; therefore, there is a need for regulations, awareness campaigns and education for consumers and health care professionals, including pharmacists.

1.4 Advocacy of teaching and learning the risks of SF medical products through online pharmacy

In recent years, there has been a significant increase in the use of the internet to obtain medical products. With the support from advertising such websites through social media, the sellers can reach increasing numbers of patients every day. Patients in the USA state that they use the internet for several reasons including convenience (66%), cost (40%), a requirement from their insurance carrier (7%), as they only way to get the medication (7%), and that they did not require a prescription (25%).¹ Similarly, patients in Saudi Arabia buy their medications online due to unavailability in the local market (47%), cost (41%), convenience (35%), good services such as home delivery (23%), availability (18%), providing health information (18%), privacy (18%), and less waiting time compared to community pharmacy (6%).¹¹

Pharmacists are the most trusted healthcare professionals and serve as medication experts for patients and communities.¹⁵ With the concerns about SF medical products obtained from illegal online drug sellers, pharmacists must have the necessary knowledge and skills to educate patients about reliable websites and avoiding illegal online drug sellers. They must be able to identify SF medical products and counsel on obtaining medical products online.¹⁵ However, according to the survey of 347 pharmacists in the US, 58% of them reported a lack of confidence in their ability to counsel patients on the identification of illegal drug sellers' websites.¹⁵ Fewer than 60% of pharmacists were able to accurately identify the legitimacy of a webpage based on visual characteristics and 75% of pharmacists reported being unfamiliar with resources available to help consumers identify safe and legitimate online pharmacies.¹⁵ Only 7% reported receiving practice site training on the provision of education to patients on illegal online drug sellers.¹⁵ In another survey which included pharmacists and doctors from the United Kingdom (UK), 69% indicated that they did not receive any training on how to educate patients in the illegal online drug sellers.²⁴ A survey of pharmacy students reported that they do not believe the university provided an adequate curriculum on SF medical products despite being aware of the disadvantages of an online pharmacy, including patients not receiving the correct product, not receiving proper information on a medication, the potential to receive SF medical products, and being unable to determine if a web page is operating legally or illegally.¹⁴

The necessary knowledge and skills for pharmacists to adequately serve patients and the public is as follows:^{2,15}

1. Pharmacists should be aware of the far-reaching nature of this problem and direct patients to legitimate websites.

2. Pharmacists must receive adequate education to ensure their interventions alter patient risk perception and increase patient use of safe, legal online pharmacies.
3. Pharmacists must have strategies for effective implementation of safe medication use in everyday practice.
4. Regardless of the distribution channel, pharmacists must be a highly accessible and reliable source of medication information.
5. Pharmacists should be aware of the issues with online pharmacies, taking care to avoid unknowingly allowing patients to bring and use unverified medication into the health system.

With adequate knowledge and skills, pharmacists can do the following for patients and the public to avoid online SF medical products:⁵

1. Pharmacy leaders should engage with colleagues and consumer groups to understand the scope and possible impact of consumerism on their pharmacy enterprise.
2. Pharmacy and healthcare leaders must take charge of ensuring a safe and secure supply chain for patients.
3. Pharmacists must provide accurate and timely information to help prevent public misinformation campaigns and limit illegal online drug sales.
4. Pharmacy personnel should be actively engaged, both inpatient and outpatient, in educating consumers, patients, and colleagues on the dangers of going online for medications without the necessary knowledge to do so safely.
5. Pharmacy leaders should be directly involved in medication reconciliation and medication discharge planning processes.
6. Pharmacy leaders can establish programmes to assist patients in obtaining medication through safe channels.
7. Pharmacy leaders should work with other health disciplines, including social workers, to ensure patients do not struggle to obtain necessary medication.

2. Modules covering online pharmacy and selling SF medical products online

In 2021, the International Pharmaceutical Federation (FIP) and WHO developed a curriculum including detailed information relating to the root causes of SF medical products. This was a project funded by the European Union (EU), supported by the WHO, and delivered by FIP.²⁴ The FIP informal technical advisory group on development of curriculum on SF medical products (2019-2023) developed the bilingual competency-based curriculum available in French and English. The curriculum was then piloted in undergraduate pharmacy students who participated in the course, which was deployed at three selected pilot pharmacy schools in sub-Saharan Africa (Cameroon, Senegal and Tanzania).²⁴ After the implementation of the course among 355 pharmacy students, it was shown that the course improved students' knowledge on SF medical products.²⁴ The WHO is now working on an updated toolkit for its member states which scales up the pilot project to be applicable beyond Africa. The toolkit will be released in Q4 2024.

Since 2021, the need to update the course was necessary to include online aspects of selling SF medical products due to the increasing threat resulting in unsafe and ineffective medications sold through online pharmacies. Therefore, five more modules were developed to be embedded into the existing course to discuss risks of obtaining online SF medical products. The modules were developed by FIP and reviewed by a FIP expert group set up for this task, in order to provide good quality of training materials for the educators.

The themes of the modules are as follows:

- Explore the problem of unsafe medication use through internet pharmacy
- Explore the current regulations about online pharmacy
- Explore the best practice regarding safe medication use: case study examples
- Explore the ways to access safe and legitimate medicine in different regions of the world
- Explore how to advise patients about the use of online pharmacy and the role of pharmacists to combat such unsafe medication use.

Each module includes objectives, learning outcomes, references and links, and one module includes four case studies about the risk of online SF medical products and solutions.

3. Developing new modules to cover aspects of SF medical products sold online

3.1 Detailed overview of the teaching and learning materials

Table 2 describes detailed information about the scope of the five new modules, including titles and subtitles.

Table 1. Overall scope of the modules

Modules	Scope
Module 1	<ul style="list-style-type: none"> • Introduction • What is online pharmacy? • Risks posed by online pharmacy • Undesirable outcomes of illegal online drug sellers • Categories of online pharmacies • Benefits of online pharmacy • Key facts about online pharmacy • Indicators for unsafe online pharmacy web sites • Survey results from pharmacists, patients and pharmacy students • FIP Survey about online pharmacy operations and distribution of medicines
Module 2	<ul style="list-style-type: none"> • Global concern on lack of regulations about online pharmacy • Global concern about patient safety • Interventions to regulate online pharmacy/purchasing medicines online
Module 3	<ul style="list-style-type: none"> • Access to safe and legitimate medicines interventions • Tools and resources to improve patient safety
Module 4	<ul style="list-style-type: none"> • Case study 1. Elective course 'Internet medicines' at Utrecht University (NL) • Case study 2. Pharmaceutical crime: global and New Zealand perspectives • Case study 3. Access to drugs online – caution needed • Case study 4. Case-study about the risks of substandard or falsified (SF) medical products sold online
Module 5	<ul style="list-style-type: none"> • What pharmacists can do for patients and the public • Essential knowledge and skills for pharmacists

3.2 Objectives and learning outcomes of the modules

The table describes the objectives and learning outcomes of the modules on online SF medical products.

Table 2. Overall objectives and learning outcomes of five modules

Objectives	Learning outcomes
Explore the problem of unsafe medication use through internet pharmacy	<ul style="list-style-type: none"> • Outline the definition and scope of online pharmacy • Learn the risks and outcomes of online pharmacy for patients and society • Discover knowledge of pharmacists/pharmacy students about online pharmacy • Identify the patterns of online pharmacy use by consumers/patients
Explore the current regulations and legislation gap about online pharmacy	<ul style="list-style-type: none"> • Identify current regulations about online pharmacy • Discover the differences in national and international legislation in the field of online pharmacy • Gain insight into the limitations of the current legislation
Explore the ways to access safe and legitimate medicine in different regions of the world	<ul style="list-style-type: none"> • Identify various initiatives from all around the world to reduce risks from online pharmacy
Explore the best practice regarding safe medication use through online pharmacy	<ul style="list-style-type: none"> • Describe an example of teaching risk of SF medical products through online pharmacies • Understand the pharmacist's role in online SF medical products • Describe regulations about online pharmacies and SF medical products • List regulation examples from various countries to avoid online SF medical products
Explore how to advise patients about the use of internet pharmacy and the role of pharmacists to combat such unsafe medication use	<ul style="list-style-type: none"> • Define what pharmacists and pharmacy leaders can do for patients and the public • Define knowledge, skills and regulations that pharmacists must have

3.3 FIPx platform

The teaching and learning materials include five slide sets and active learning questions in the FIPx platform. Educators can reach the materials at <https://provision.fip.org/fipx-courses/> under “substandard and falsified medicines online course (2024)”. Registration to the FIPX platform is required prior to the access of the materials. Please contact FIP Office at profession@fip.org for more information on access.

4. Handbook for teachers on the use of new modules

4.1 Who is this handbook for?

This guide serves as a handbook that aims to support educators and trainers of pharmacy students involved with the delivery of the online SF medical products. This guide can be further extended for use in education and training of other non-pharmacy healthcare professionals.

4.2 What is this handbook for?

This guide provides educators and trainers with teaching materials, resources and practical guidance on preparing pharmacy undergraduates for practice with the relevant information for illicit online pharmacies which sell SF medical products.

4.3 How do I use this handbook?

This guide can be used together with the existing SF curricula guide noted above. It provides new sections to support learning of illicit online pharmacies which sell SF medical products.

4.4 Who is the target audience for the modules?

The modules are for pharmacy students, but also include programmes to support training the next generation of pharmacists, to be used by educators and trainers. The modules can also be used to train other relevant healthcare students.

5. Conclusions

Pharmacists have a crucial role in avoiding SF medical products by counselling patients on where to obtain reliable medical products, and identifying and detecting SF medical products and/or illegal online drug sellers. Pharmacists must also develop solutions and regulations to avoid obtaining SF medical products online.

This handbook has been developed to guide educators and trainers on the risk of SF medical products obtained from illegal online drug sellers. The training materials were designed specifically for the concerns of SF medical products obtained through illegal online resources. We hope that with the addition of five new modules to the existing curricula, pharmacy students will learn and be trained further about the risks of online SF medical products. This resulting curricula is now strengthened to teach the broader issue of SF medical products globally.

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