3.2 Module B. Prevent

Module overview

Module B discusses how SFMPs can be prevented from entering the supply chain, during all the steps of their life cycle, that is, manufacturing, distribution and use or expiry. The preventive actions require a coordinated and multidisciplinary approach, encompassing regulatory oversight, quality assurance, quality control, supply, communication, and collaboration at local and global levels to maximize the efforts to prevent SFMPs.

Learning objectives

At the end of Module B, learners in levels 1, 2, and 3 should be able to demonstrate the competencies (knowledge, skills and attitudes) outlined in Tables 21, 22 and 23. **Note.** Level 2 learners must demonstrate competency in the elements of levels 1 and 2, while level 3 learners must demonstrate competency in the elements of levels 1, 2 and 3.

Table 21. Level 1: health services providers' knowledge, skills and attitudes competencies

Competency	Ability
Knowledge	• List the critical steps in the supply chain for SFMP entry and main actions to preserve supply-chain integrity. • Describe the roles of a well functioning national and regional regulatory authority. • Explain the principles of GMP and their importance in the prevention of substandard medical products. • Give examples of relevant multilateral and advocacy initiatives to combat SFMPs.
Skills	• Implement preventive actions appropriate to learner's level in the health system to combat SFMPs. • Explain which of these strategies are applicable (and how) to the roles of health care professionals and formulate examples for the different roles (e.g. during clinical consultation and dispensing of medicines). • Communicate and educate communities effectively on the harms of SFMPs and how to prevent them. • Apply the national or WHO guidelines for the donation of medicines, ensuring compliance with best practices for safe and effective medicine donations, particularly in emergency response situations.
Attitudes	• Act as a trusted source of information and educate communities about the risks of obtaining medicines through unauthorized online sources and through non-regulated channels. • See their future participation in preventing SFMPs as a positive opportunity for holistic care, rather than an extra burden. • Consider communication as part of a holistic approach to health care. • Communicate with communities in a clear, respectful and non-judgmental way. • Support initiatives that raise public awareness about the dangers of SFMPs, empowering communities to make informed decisions about their health care.

GMP: good manufacturing practice; SFMP: substandard and falsified medical product; WHO: World Health Organization.

Table 22. Level 2: health management personnel's knowledge, skills and attitudes competencies

Competency	Ability
Knowledge	• List the most relevant technical guidelines and frameworks for SFMP prevention. • Integrate SFMP strategies into public health policies and programmes.
Skills	• Identify, prioritize and implement relevant prevention actions to maintain the integrity of the supply chain and prevent the entry of SFMPs. • Develop and present structured communication plans on SFMPs for various communities or groups of health and care workers. • Link with public health oriented initiatives in their own country, if any.
Attitudes	• Encourage colleagues, team members, management and, when applicable, policy-makers to get involved in prevention measures. • Seek out public health information on SFMPs and be ready to disseminate it, via informal and formal networks, and education and continued professional training.

SFMP: substandard and falsified medical product.

Table 23. Level 3: regulators and policy-makers' knowledge, skills and attitudes competencies

Competency	Ability
Knowledge	• Discuss the various strategies to prevent SFMPs, in terms of regulation, manufacturing, procurement and supply. • Explain how the different levels of preventive interventions connect to each other. • Identify effective communication strategies and select the most appropriate for different audiences. • Know the regulatory harmonization initiatives presented in the module and understand how they are interconnected.
Skills	• Identify (or map) vulnerabilities in the supply chain. • Approach donations of medical products as a potential risk of SFMPs. • Create convincing communication initiatives to combat SFMPs for communities, groups of health and care workers, and, if applicable, policy-makers (based on IDEAS framework) *(17)*. • Link with regulatory and/or public health-oriented initiatives in their own country, if any, and internationally. • Assess the risks and consequences of conflict of interest on information on medical products.
Attitudes	• Advocate for the incorporation of strategies to prevent SFMPs in national health (and other) policies. • Be advocacy-minded and interested in public health information on SFMPs and open to disseminating it via informal and formal networks and policy-making, among others. • Promote regional and international collaboration for the prevention of SFMPs.

SFMP: substandard and falsified medical product.

Recommended learning activities

- Allocate sufficient time for this module (about 4 to 8 hours) for practical exercises and discussions.
- Ask learners to create a visual/narrative description of their country's medical product system and manufacturing and supply chain, and to indicate the possible entry points of SFMPs. Ask other learners to provide constructive feedback on their efforts in relation to the knowledge, skills and attitudes.
- Plan a group work exercise. Give each group one or more WHO Medical Product Alert and ask them to imagine how and by whom these SFMPs could have been prevented. For example, could it be: at the manufacturing site by more rigorous implementation of functional testing of incoming goods; at the distributor level by enforcing adequate storage conditions to prevent the occurrence of substandard products; at the border through risk-based control to prevent the importation of falsified or unauthorized products. Try to select different cases, such as SFMPs that were imported and/or locally manufactured, or that were innovator or generic products.
- Provide other examples from the literature and WHO Medical Product Alerts, possibly with a focus on the region where the training is taking place. If involved, the NRRAs could be asked to provide local cases.
- Insist on the need to coordinate the work of different stakeholders (e.g. NRRAs, manufacturers, suppliers, WHO, regulatory harmonization initiatives, health insurance, law enforcement and customs agencies).

3.2.1 Strategies to prevent SFMPs (along the product life cycle)

Preventing SFMPs from entering the supply chain

Adequate management of procurement, storage, distribution and supply of medical products is intended to ensure the integrity of the products in the **formal supply chain**, including preventing infiltration of SFMPs. The following factors should be considered.

- Implementation of adequate prequalification criteria for sourcing medical products will minimize the risk of procuring substandard medical products.
- Implementation of adequate storage and distribution practices will minimize the risk of accelerated deterioration of quality-assured products, leading to loss of therapeutic efficacy and even to toxicity.
- Implementation of stock control management systems that support batch numbering will minimize the risk of recalled and expired medical products that need to be removed, and allow items with shorter dates of expiry to be issued first.
- Proper management of expired and out-of-use medical products will avoid them being diverted to the informal market or inadvertently reintroduced into the formal market. Disposal must be in accordance with national and international standards to prevent harm to staff, the community and the environment.
- Avoiding prescription of medicines that are not easily accessible to the patient, such as those known to be unavailable in the hospital or at dispensing points, or expensive medicines not covered by health insurance, will deter patients from trying to access medicines elsewhere, for example, from illegal or unknown sources.
- Good dispensing and supply practices at the pharmacy, point-of-care or retail level, including adequate repackaging, multi-use vials and reconstitution, will also avoid unwanted deterioration of the products.
- Effective needs planning by health facilities and wholesalers, and good inventory management will minimize the risk of shortages or expiry of medical products (understock or overstock). Shortages can lead to the need to place emergency orders that cannot be placed with prequalified suppliers.

- Donations of medicines and medical products present unique challenges. According to WHO guidelines, donations should "respect the wishes and authority of the recipient, while adhering to the government policies, regulatory requirements and administrative arrangements of the recipient country"*(18)*. When these principles are not followed, such donations can disrupt planned procurement processes and increase the risk of SFMPs. Developing national policies on donations of medical products, aligned with the WHO guidelines for medicine donations, is essential to prevent the entry of inappropriate or non-compliant donations.

WHO provides comprehensive guidance for good practices in procurement, supply and dispensing of medical products. It is recommended that, before starting a training, the trainer checks on the WHO website for any updated versions of such key documents. The following are some of the main publications.

- Model quality assurance system for procurement agencies *(14)*
- Good storage and distribution practices (GSDP) for medical products *(19)*
- Guidance for procurement of in vitro diagnostics and related laboratory items and equipment *(20)*
- Guidelines on good pharmacy practices *(21)*
- Guidelines for medicine donations *(18)*

The **informal supply chain, including unauthorized online suppliers**, is unregulated and intrinsically at high risk of infiltration of SFMPs. Strengthening of regulatory and legal oversight, accompanied by universal access to essential medical products through the formal system should eliminate the demand for an informal market in the long term. Meanwhile, partial protective measures can be implemented, including educating the public and the health staff about the dangers of the informal market.

Pharmacists and other staff working in the medical product systems share joint responsibility for assuring the integrity of the overall supply chain, in different ways, as outlined below.

- Pharmacists and other workers in community pharmacies and health facilities at all levels of a health system, from health posts and health centres to district and tertiary hospitals. Procure all medical products at licensed wholesalers/distributors only, even under pressure due to shortages; implement traceability of all medical products; assure adequate inventory management; assure adequate storage and transport conditions for all medical products, whether heat-sensitive or heat-stable; adopt good practices with repackaging/reconstitution of medicines from bulk packaging; and sensitize patients, caregivers and health and care workers about the importance of avoiding the informal market and unauthorized online vendors.
- Prescribers. Prescribe medical products according to national standards treatment guidelines and national medicines lists; ensure that all aspects of treatment and therapeutic objectives have been discussed with the patient; and sensitize patients about the importance of avoiding the informal market and illegal online vendors.
- National and international procurement agencies. Implement good procurement practices, including by using adequate technical and quality specifications in tenders. For instance, it is good practice that products with marketing authorization are admitted in national tenders, and that otherwise quality-assured (e.g. WHO prequalified) products are accepted in international tenders. Regulatory databases can be consulted, in addition to the WHO prequalification lists, such as those of the European Union (Eudra GMDP for medicines and EUDAMED for medical devices) and the Food and Drug Administration (GUDID for medical devices) and various registers of the Health Sciences Authority of Singapore, Ministry of Food and Safety of Republic of Korea and Swissmedic as WHO-listed authorities.

Regulatory (oversight) strengthening

NRRAs should ensure the quality of medical products manufactured, imported and distributed in a country (including donations). In well functioning systems, NRRAs set and ensure compliance with regulations and norms to guarantee the quality of medical products throughout the supply chain, based on WHO standards. Moreover, WHO developed global benchmarking indicators which provide a mapping on which such indicators apply to the WHO PDR strategy.

Well functioning regulatory systems have rigorous mechanisms for:

- registration and marketing authorization
- licensing of establishments and regulatory inspections
- laboratory testing
- oversight of clinical trials
- NRRA lot release (in the case of vaccines), that is, the review and approval of each manufactured batch
- vigilance, market surveillance and control
- exceptional import authorizations, particular donations and other exceptions (e.g. compassionate use).

An effective regulatory system will establish a process for applicants for market authorization to submit technical documents demonstrating quality, safety and efficacy of medical products. The system will also have a process for distributors, wholesalers and importers to submit technical documentation demonstrating quality of transportation, storage and distribution. Pharmacists and other professionals working at NRRAs, or at regional regulatory bodies (such as the European Medicines Agency, Food and Drug Administration and African Medicines Agency) must have the skills and expertise needed to oversee and control those involved in the national and international pharmaceutical chain. For example, their work will involve the following responsibilities.

- Implement regulatory measures for supply-chain management, including traceability at national and international levels, bearing in mind that the global pharmaceutical market is characterized by intermediate steps for both manufacturing and distribution.
- Strengthen collaboration with customs, legal authorities and other law enforcement bodies, to assure regulatory, criminal, financial and administrative sanctions are imposed on those who supply SFMPs. The various players involved include but are not limited to the health, justice and trade ministries, law enforcement agencies, customs authorities, and professional bodies.
- Adhere to international initiatives that pool efforts to prevent SFMPs, such as the MEDICRIME Convention *(22)*.
- Implement regulatory and legal measures against the illegal online sale of medical products.
- Improve data collection on SFMPs by merging information from different sources (e.g. the NRRA, pharmacovigilance programmes, WHO alerts, customs, lay press) to identify trends and potential clusters of SFMPs (e.g. certain manufacturers or distributors, or certain areas).

See section 3.2.3 for examples of multilateral organizations or initiatives to support the strengthening of NRRA.

Preventing manufacturing of substandard medical products

While falsified medical products result from criminal and unregulated activities, substandard medical products result from poor implementation of GMP, either occasionally or systematically, due to poor skills, insufficient infrastructures and resources, negligence, or a combination of these factors. According to WHO, GMP is *(23)*:

> the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification. GMP defines quality measures for both production and quality control and defines general measures to ensure that processes necessary for production and testing are clearly defined, validated, reviewed, and documented, and that the personnel, premises and materials are suitable for the production of pharmaceuticals and biologicals including vaccines. GMP also has legal components, covering responsibilities for distribution, contract manufacturing and testing, and responses to product defects and complaints. Specific GMP requirements relevant to classes of products such as sterile pharmaceuticals or biological medicinal products are provided in a series of annexes to the general GMP requirements.

WHO highlights that "more than 100 countries have incorporated its GMP provisions into their national medicines laws, and many more countries have adopted its provisions and approach in defining their own national GMP requirements. The WHO GMP continues to be used as a basis for the WHO certification scheme and prequalification of vaccines for procurement by United Nations (UN) agencies" *(24).*

A rigorous implementation of GMP helps prevent substandard production. Moreover, innovator and generic manufacturers can consider using technology for making the genuine products clearly identifiable compared with falsified versions. For instance, holograms, invisible reflection inks or filters, security graphics, security labels (tamper-evident seals) and serialization have been used to demonstrate authentication of some medicines by the manufacturer, regulatory inspectors, custom officers and other relevant staff.

Supply-chain management

Globalization of the supply chain, new technologies, global transportation and global communication have led to an increasingly complex supply chain. This involves several actors in a variety of countries: procurement and distribution of medical products is managed by various public, private and nongovernmental actors in low- and middle-income countries, including subcontractors for some manufacturing steps, importers, procurement agencies, and distributors, wholesalers and retailers. This complexity brings the following new challenges, among others.

- It is more difficult for NRRAs, particularly those with insufficient resources, to oversee all the manufacturing and distribution steps.
- It is more difficult to ensure traceability of products up to the manufacturer (of the finished product and of active ingredients and excipients).
- The risk of irregular supply and shortages is greater, which in turn creates an opportunity for unregistered and falsified products.
- Overall, more opportunities exist for poor practices and infiltration of SFMPs.

Here, the trainer can consider providing examples of the supply chain in the country or region where the training is taking place and look at the potential vulnerabilities.

3.2.2 Communication, education and awareness-raising

Raising awareness of patients, communities and health professionals

Even if it is primarily the responsibility of NRRAs and policy-makers to prevent SFMPs, raising public awareness is important to inform and empower the patients and the communities. Unfortunately, they are generally poorly or not informed about SFMPs, and the same applies to many prescribers and other health care professionals.

Many strategies have been proposed to raise awareness among **patients and communities**.

- Communication strategies should adopt the insight–data–engagement–action–solution (IDEAS) model *(16)* to help create convincing communication initiatives.
- Communication may target the general public or specific target groups (e.g. young people, caregivers, people with a given disease, specific professional groups and community leaders in rural areas).
- The most popular communication channels in a given community should be chosen (e.g. radio, social media or patient associations). The use of well known local individuals as ambassadors (e.g. popular persons from music, sport, culture, religion or other fields, as well as testimony from patients/families with an experience of SFMPs) is also an effective way to deliver the message in the community.
- The communication plans should be tailored to the context and, if applicable, to the selected target group. For instance, the information should be available in all the local languages, technical jargon should be avoided and audiovisual tools could be developed to make the concepts understandable to a lay audience.
- The wording must be carefully weighed in order to inform and sensitize without causing unnecessary anxiety or panic, or being judgemental or patronizing.
- Previous experiences should be considered; for instance, a community already affected by a major quality incident will have a different perception compared with other contexts.
- The communication plans should aim to achieve social and behaviour changes; for instance a better capacity of the target group to avoid dangerous sources of medical products and to report suspect cases to prescribers.
- Even if the focus is on SFMPs, this topic should be linked to other issues, such as affordability and availability of medical products. For instance, as well as explaining the dangers of the informal market, practical information also needs to be provided on where to find quality-assured and affordable medicines.

Raising awareness among **health care professionals** requires the communication to cover more technical aspects, among other things, and should cover:

- the possible sources and risk factors of SFMPs, in general and in the specific context of the target audience;
- the possible indicators of SFMPs, such as unexpected lack of therapeutic or preventive efficacy, unexpected side-effects, and unusual physical appearance of the products, with visual examples if possible;
- the importance and the methods of reporting to NRRAs and pharmacovigilance systems (see module D); and
- the sources of medical information for medical treatment in case of toxicity due to SFMPs.

It may be useful to highlight the definitions of generic (multisource) medicines and biosimilars, as there may be confusion between therapeutically equivalent medical products and SFMPs.

The content and methods of the communication should be adapted to the target group (e.g. nurses, general practitioners, laboratory technicians, public health specialists, community health workers and traditional birth attendants). Furthermore, communication campaigns should always include clear instructions on what action to take in the event of suspected SFMPs and consider whether this is feasible for the target audience.

Any potential conflict of interest, such as support from a pharmaceutical company in developing the communication materials, should be transparently declared.

Local, regional and national policy-makers and commercial partners are often unaware of the challenges of SFMPs. Health professionals can play a role in engaging with such stakeholders.

Role of health care professionals in educating patients

Well informed and sensitized health care professionals can and should play a role in raising awareness among their communities and providing information to their patients and caregivers on an ongoing basis.

- Pharmacists, while dispensing and advising clients, can explain the risks of obtaining medicines from unauthorized sources and empower and encourage patients to be vigilant of any signs of SFMPs, such as changes in packaging, appearance and expiry date, and report suspected cases. They can also be the link between the reporting patient, medical services and pharmacovigilance systems.
- Nurses, general practitioners and other prescribers can explain the risks of obtaining medicines from unauthorized sources during consultations, and can identify possible indicators that somebody may have taken an SFMP, based on clinical presentation and symptoms.
- Community health workers can explain the risks of obtaining medicines from unauthorized sources and provide positive information on where quality-assured products may be obtained.

3.2.3 Global efforts to combat SFMPs

Role of WHO in regulatory strengthening

As described in the earlier section Preventing manufacturing of substandard medical products, well functioning regulatory systems are vital to prevent SFMPs. WHO plays an important role, through the following initiatives and programmes.

- The development of norms, standards and guidelines to promote quality assurance for pharmaceuticals is an integral part of WHO's Constitution. The WHO norms and standards are intended for use by NRRAs, pharmaceutical manufacturers and other interested parties. They are based on recommendations of WHO governing bodies, the International Conference of Drug Regulatory Authorities, the WHO Expert Committee on Specifications for Pharmaceutical Preparations, international organizations and UN agencies, and other WHO programmes and activities. Some are developed in response to important public health needs and are thereafter adopted by the Expert Committee on Specifications for Pharmaceutical Preparation. The previously mentioned model quality assurance system for procurement agencies and GSDP guidelines are part of this exercise.
- The WHO prequalification initiative aims to ensure that key health products meet global standards of quality, safety and efficacy in order to optimize use of health resources and improve health outcomes *(25)*. The prequalification process consists of a transparent, scientifically sound assessment, which may include dossier review, product testing, performance evaluation, and inspection of manufacturing sites and research organizations. Prequalification outputs — including lists of prequalified products, list of prequalified quality control laboratories and WHO public assessment and inspection reports — are used by the UN and other procurement agencies to guide their purchasing decisions. The prequalification process covers: medicines for HIV/AIDS, malaria, tuberculosis, reproductive health, hepatitis, diarrhoeal diseases and selected neglected tropical diseases, as well as a few biotherapeutic products; a wide array of diagnostics for both endemic and epidemic diseases in low- and middle-income countries;

all vaccines required for routine immunization against 24 priority diseases; all equipment needed for an effective national vaccine programme; and new products used for the prevention of vector-borne disease.

- The WHO GSMS for SFMPs was launched in 2013 to improve the quantity, quality and analysis of accurate data on SFMPs, and to use those data to improve prevention, detection and response to SFMPs and protect public health *(1)*. The WHO global reporting system is designed for use by trained focal points in NRRAs. Reports of SFMPs are submitted to WHO via an electronic rapid alert form, where they are cross-referenced and uploaded to a secure database. WHO's team for incidents and SMFP has a key function in identifying incidents of SMFP and sharing with reporting Member State and focal points within 72 hours. In emergencies, this may take the form of facilitating urgent laboratory analysis or in extreme and complex cases deploying experts in the field.
- The WHO GBT for evaluation of national regulatory systems is the main means by which WHO objectively evaluates regulatory systems. The tool and benchmarking method enable WHO and regulatory authorities to: identify strengths and areas for improvement; facilitate the formulation of an institutional development plan to build on the strengths and address the identified gaps; prioritize institutional development plan interventions; and monitor progress and achievements.

Multilateral organizations or initiatives

The list below of organizations and initiatives is for illustrative purposes. It is not exhaustive, nor does the listing of these organizations and/or initiatives represent an endorsement by WHO.

International organizations

- Combating falsified medical product-related crime: a guide to good legislative practices. Vienna: United Nations Office on Drugs and Crime; 2019 (https://www.unodc.org/documents/treaties/publications/19- 00741_Guide_Falsified_Medical_Products_ebook.pdf, accessed 17 November 2024).
- International Criminal Police Organization (INTERPOL) endeavours to create modern approaches to tackle pharmaceutical crime in partnership with law enforcement agencies, international organizations, industry, and member states (https://www.interpol.int/en/Crimes/Illicit-goods/Shop-safely/Fake-medicines, accessed 17 November 2024).
- MEDICRIME Convention (Council of Europe) offers a legal framework for worldwide cooperation to combat the falsification of medical products and pharmaceutical crimes (https://www.coe.int/fr/web/medicrime/the-medicrime-convention, accessed 17 November 2024).
- Private sector
- International Federation of Pharmaceutical Manufacturers and Associations partners with pharmacy professional associations are often involved in campaigns to raise awareness and do advocacy (https://www.ifpma.org/areas-of-work/improving-health-security/falsified-medicines/, accessed 17 November 2024).

NGOs and pharmacist associations

- International Pharmaceutical Federation. Substandard and falsified medical products: regulatory self-assessment tool. The Hague: International Pharmaceutical Federation; 2023 (https://www.fip.org/file/5653, accessed 17 November 2024). Tools are also available for pharmacists on its website.
- Fight the Fakes campaign whose goal is to raise awareness about the dangers of SFMPs (https://fightthefakes.org/, accessed 17 November 2024).
- Counterfeit medicines: 2022–2024 Outlook of the Lomé Initiative. London: Brazzaville Foundation: 2022 (https://www.brazzavillefoundation.org/medicaments-falsifies-perspectives-2022-2024-de-l-initiative-de-lome/, accessed 17 November 2024). The Lome Initiative is an African regional level initiative by the Brazzaville Foundation.

- The Commonwealth Pharmacists Association does advocacy to fight SFMPs (https://commonwealthpharmacy.org/, accessed 17 November 2024).
- Ecumenical Pharmaceutical Network is an independent, non-profit organization operating in Africa which is committed to providing quality-assured pharmaceutical services. It started the Minilab project in 2010, which has informed both scientific literature and some WHO Medical Product Alerts (https://www.epnetwork.org/accueil/, accessed 17 November 2024).
- Asia-Europe Forum on Combatting Substandard & Falsified Medicines (https://asef.org/wp-content/uploads/2020/10/CN_Asia_Europe_Forum_on_Combating_SFMs-Final.pdf, accessed 9 December 2024).

Regulatory harmonization initiatives

- International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (https://www.ich.org/, accessed 17 November 2024).
- European Medicine Agency (https://www.ema.europa.eu/en/homepage, accessed 17 November 2024).
- Pan American Network for Drug Regulatory Harmonization (https://www.paho.org/en/pan-american-network-drug-regulatory-harmonization-pandrh, accessed 17 November 2024).
- The East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme (https://www.eac.int/mrh, accessed 17 November 2024).
- African Medicine Regulatory Harmonization programme (https://amrh.nepad.org/, accessed 17 November 2024).
- African Medicines Quality Forum Technical Committee (AMQF-TC) on strengthening quality control systems (https://amrh.nepad.org/african-medicines-quality-forum-technical-committee-amqf-tc, accessed 17 November 2024).
- Association of Southeast Asian Nations. Joint Assessment Coordination Group
- Asia-Pacific Economic Cooperation. Regulatory Harmonization Steering Committee (https://www.apec.org/rhsc, accessed 17 November 2024).
- Asia-Pacific Economic Cooperation. Supply chain security toolkit (https://www.usp.org/apec-supply-chain-security-toolkit, accessed 17 November 2024).
- Pharmaceutical Inspection Co-operation Scheme (https://picscheme.org/en/picscheme, accessed 17 November 2024).

Download practical resources and supplementary training material relevant to Module B

Identifying suspected SFMPs

Characteristics of suspect websites likely to distribute SFMPs

Prioritization and risk parameters

Questions to consider when assessing risk