

Frequently asked questions

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Does quality of medicines matter?

Yes, it matters.

Medicines including vaccines save lives and prevent diseases and epidemics only if they are safe, efficacious, of good quality and are used rationally. The use of unsafe, substandard, ineffective and Spurious/falsely-labelled/falsified/counterfeit medical products (SFFC) and vaccines can be harmful to the health and well being of the individual patient as well as to a wider section of the population. They also undermine confidence in the health service, health professionals who treat patients, prescribers, as well as those who manufacture, distribute and dispense/sale medicines.

The purchase of unsafe, substandard, ineffective and SFFC medicines is a waste of money for the government, the individual patient and the public.

What should be done to ensure the safety, efficacy and quality of medicines?

Governments must regulate the manufacture, export, import, storage, distribution, supply and sale of medicines to ensure the safety, efficacy and quality of medicines.

Governments have to establish strong national medicines regulatory authorities (NMRAs). To enable the NMRAs to operate effectively, governments have to provide strong political support, adequate and sustainable human, financial and other resources, and legal power for enforcement. Ineffective regulation and control can result in the proliferation of unsafe, ineffective, substandard and SFFC medicines.

In addition, manufacturers have to produce medicines in accordance with good manufacturing practice (GMP) requirements and distributors have to store and distribute medicines in accordance with good storage and good distribution practices as provided in the WHO guidelines ([Guide to good storage practices for pharmaceuticals](http://whqlibdoc.who.int/trs/WHO_TRS_908.pdf#page=135), Annex 9, WHO Technical Report Series 908, 2003: http://whqlibdoc.who.int/trs/WHO_TRS_908.pdf#page=135 and [Good distribution practices for pharmaceutical products](http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf#page=191), Annex 5, WHO Technical Report Series 937, 2006: http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf#page=191).

What are spurious/falsely-labelled/falsified/ counterfeit medical products (SFFC)?

SFFC medicines are defined differently in different countries. The definitions used in the various WHO Member States show that the nature of the problem of SFFC medicines varies from country to country.

The first international meeting on SFFC medicines was held from 1 to 3 April 1992 at WHO in Geneva and gathered experts from governmental institutions of WHO member states, INTERPOL, World Customs Organization (at the time known as Customs Cooperation Council), International Narcotics Control Board, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), International Organization of Consumer Unions, and the International Pharmaceutical Federation (FIP) in response to a World Health Assembly resolution (WHA41.16). The participants agreed on the following definition:

A "counterfeit" medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and "counterfeit" products may include products with the correct ingredients or with the wrong

ingredients, without active ingredients, with insufficient (inadequate quantities of) active ingredient(s) or with fake packaging.

(Ref: Guidelines to develop measures to combat "counterfeit" drugs, WHO/EDM/QSM 99.1 (1999) http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf)

Is a uniform definition of a SFFC medicine necessary?

Yes, it is necessary if we want to understand and combat the problem.

The absence of a universally accepted definition makes information exchange between countries very difficult, limits the ability to understand the true extent of the problem at global level, and hinders the development of global strategies to combat the problem. In order to address this issue the World Health Organization (WHO) had formulated a definition already in 1992. Discussions on further improving this definition for legal use have continued under IMPACT.

What are substandard medicines?

"Substandard medicines are pharmaceutical products that fail to meet either their quality standards and specifications, or both.

Each pharmaceutical product that a manufacturer produces has to comply with quality assurance standards and specifications, at release and throughout its shelf-life, according to the requirements of the territory of use. Normally, these standards and specifications are reviewed, assessed and approved by the applicable national or regional medicines regulatory authority before the product is authorized for marketing."

45th WHO Expert Committee on Specifications for Pharmaceutical Preparations, 2010

How do substandard medicines arise?

They arise mostly due to the application of poor manufacturing practices by the producer or when a good quality medicine is stored and distributed under improper conditions leading to deterioration of the quality of the product.

Is there possibility for a substandard medicine to be considered as SFFC?

Yes, there is possibility.

This could happen if a legitimate manufacturer gets involved in a criminal activity and produces a substandard product intentionally or deliberately. After all, what makes a product SFFC is the criminal act involved.

Is it possible for a legitimate manufacturer to produce a substandard medicine deliberately?

Why not?

Any one who has intention to make money unlawfully can produce a substandard medicine deliberately. There is nothing to prevent him/her from producing as so long as he/she can avoid detection and prosecution. It is more likely to happen in countries where medicine regulation is ineffective and/or law enforcement is weak.

Are there good quality SFFC medicines?

No. There are no good quality SFFC medicines.

By definition SFFC medicines are products whose true identity and or source are unknown or hidden. They are mislabelled with respect to identity and or source and are produced by criminals.

It is true that, sometimes, a SFFC medicine may pass laboratory tests but this does not mean that it is a good quality medicine. GMP requires that the label on the container of a medicine should indicate, among others, the name of the active ingredient, the name of the manufacturer and the country of manufacture. If a manufacturer intentionally hides or gives wrong information regarding

any of these the product becomes SFFC. It is, therefore, unwise to assume that there are good quality SFFC medicines. Counterfeiters should not be expected to produce good quality medicines since their motive is to make money unlawfully.

Where are SFFC medicines found?

SFFC medicines have been reported to occur worldwide.

The problem of SFFC medicines is not limited to developing countries only. They are also found in developed countries. But, the problem is more in countries where medicine regulation is ineffective, smuggling of medicines is rampant, clandestine manufacturing exists, sanctions are absent or very weak, and there is high corruption. No country is immune to the problem.

How big is the problem of SFFC medicines?

The true extent of the problem of SFFC medicines is not really known.

Counterfeiting is an underworld activity. It is hard to detect and investigate. Moreover, countries and companies that detect the problem do not always report. So, it is hard to know or even estimate the true extent of the problem. What is known is that they occur worldwide and are more in developing countries.

What kind of products are counterfeited most?

According to reports received from national authorities in countries and information published in newspapers and journals, both well established (generic) medicines and innovative medicine products are affected. Generally, high volume (high consumption) and expensive medicines are the main targets of counterfeiters.

The largest number of reports relate to antibiotics, antiprotozoals, hormones and steroids. In developing countries, antibiotics and antiprotozoals such as anti-malarial medicines are commonly

counterfeited. In developed countries hormones and steroids account for the majority of the cases reported.

What are the different types of SFFC medicines that have been reported?

SFFC medicines reported so far can be grouped into different categories.

These are:

1. products without active ingredients;
2. products with inadequate quantities of active ingredients;
3. products with incorrect active ingredients; and
4. products with correct quantities of active ingredients but with the wrong name of manufacturer and/or country of manufacture indicated on the label.

Purchase of medicines via the Internet

Purchase of medicines via the Internet has a high chance of exposing patients/consumers to SFFC and substandard medicines. The patient/consumer has no way of knowing if the product is manufactured by an authorized manufacturer; if manufacturer complies with GMP requirements or the products is approved by the NMRA of the country claimed to be country of manufacture. There is no way of knowing if the seller/supplier is genuine. Further more the quality and composition of medicine obtained from the Internet cannot be guaranteed as there may not be checks and controls

on the quality and effectiveness of medicines supplied; and there may be no legal recourse in the event of problem.

What is the public health risk of SFFC medicines?

The use of SFFC medicines can be harmful to the health and well being of the individual patient as well as to a wider section of the population. Their use may result in treatment failure or even death. They also undermine confidence in the health service, health professionals who treat patients, prescribers, as well as those who manufacture, distribute and dispense/sale medicines.

What encourages counterfeiting of medicines?

Medicines are attractive for counterfeiting

Medicines are high value items in relation to their bulk and the demand for medicines is infinite;

Producing SFFC medicines may not require building huge infrastructure or facilities. They can be produced in small "cottage" industries, or in backyards or even under the shade of a tree;

For a counterfeiter, ingredient costs can be very low if cheap substitutes are used or omitted altogether as is often the case. There are also no overhead costs due to costs of quality assurance or meeting GMP standards since such standards are never implemented;

A SFFC medicine has better capacity to deceive particularly if it is copied to make it look like the original product. Patients and/or purchasers are not able to detect whether the product they are buying is of good quality let alone to detect whether the product is SFFC.

Lack of political will and commitment to establish strong national medicines regulatory authorities (NMRA)

The development, manufacture, importation and subsequent handling of medicines within the distribution channels should conform to prescribed standards, and the quality of medicines should be rigorously controlled. However, this would require strong NMRA. This in turn needs strong government will and commitment to provide adequate human, financial, and other resources, appropriate infrastructure and legal power to enforce medicine regulation. In many WHO Member States the political will and commitment to establish strong NMRAs or to strengthen existing ones is weak or lacking. Consequently, medicine regulation and control activities are ineffective and inefficient resulting in - noncompliance of local manufacturing with requirements of good manufacturing practices; circulation of unregistered/unapproved medicines in the national market; smuggling of medicines through port of entries and boarders, etc.

Lack of appropriate medicine legislation

Legislation and regulations form the basis for medicine regulation. Where legislation and regulations do not exist or are inadequate for proper control of medicines, criminals are encouraged to produce SFFC medicines.

Currently, only a few of the WHO Member States have enacted special national legislation on SFFC medicines. Moreover, sanctions imposed on counterfeiters are, in most cases, not deterrent.

The absence of legislation prohibiting the manufacture of and trade in SFFC medicines or the absence of deterrent sanctions encourages counterfeiters since there is no fear of being apprehended and prosecuted.

Absence of or weak national medicines regulatory authorities (NMRA)

Ensuring the safety, efficacy and quality of medicines requires the creation of a competent national medicine regulatory authority with the necessary human, and other resources to control the manufacture, importation, distribution and sale of medicines.

At present, out of the 193 WHO Member States about 20% are known to have well-developed medicine regulation. Of the remaining Member States, about 50% implement medicine regulation at varying levels of development and operational capacity. The remaining 30% either have no medicine regulation in place or a very limited capacity that hardly functions. Ineffective or weak medicine control could promote smuggling, and illegal manufacture and distribution of medicines leading to the proliferation of SFFC medicines on national market.

Weak enforcement

Enacting deterrent legislation alone will not solve the problem of SFFC medicines. Legislation needs to be enforced. Where existing legislation is not enforced crime is perpetuated as criminals are not afraid of being arrested and prosecuted. In most countries cooperation between NMRA, police and customs is either weak or non-existent, which makes it difficult to detect, arrest and bring criminals to court.

Corruption and conflict of interest

The efficiency of personnel working in medicine regulation and those involved in law enforcement activities such as police, customs and the judiciary, is adversely affected by conflict of interest and corruption resulting in laws not being enforced and criminals not being arrested, prosecuted and convicted for their crimes. In order to address the problem corruption, governments need to develop policies on conflict of interest and establish mechanisms for managing conflict of interest. Personnel working in medicine regulation as well those participating in national medicines anti-counterfeiting programmes should be required to sign conflict of interest form.

Empowering consumers and public interest groups to participate in medicine regulation, making NMRAs transparent and accountable and motivating NMRA staff and enforcement officers by providing them incentives can help in combating conflict of interest and corruption.

Shortage or erratic supply of medicines

When the supply of medicines in a country is short or erratic, patients and consumers tend to look for alternative sources. Such situations encourage criminals to smuggle in medicines or manufacture SFFC medicines and distribute them as a substitute for genuine medicines.

Inappropriate use of medicines

Consumers who use medicines inappropriately generate demand for such medicines, the sources of which may be SFFC. For example, the misuse of creams containing steroids for skin bleaching and body building medicines has generated a market for SFFC steroid-containing medicines. Often, these medicines are distributed through unauthorised channels or illicit markets.

High prices of medicines

When the prices of medicines become excessively high and unaffordable, patients tend to look for cheaper sources. Such situation encourages counterfeiters to produce cheaper SFFC medicines.

Price differentials

When price differences exist between identical products, patients and consumers go for the cheaper ones. This creates a greater incentive for counterfeiters to supply cheap SFFC medicines.

Inefficient co-operation between stakeholders

Intersectoral cooperation between NMRAs, police, and customs services and the judiciary is essential for effective control of the national medicine market and enforcement of medicine legislation. When such cooperation is ineffective, counterfeiters can escape detection, arrest and penal sanctions.

Equally, the cooperation of the pharmaceutical industry, wholesalers and retailers to report to the NDRA cases of SFFC medicines is necessary in combating SFFC medicines. Where such cooperation

is lacking the NDRA may not be able to take measures against counterfeiters hence SFFC medicines tend to flourish.

Lack of control over export medicines

When countries do not control export medicines to the same standard as those produced for domestic use, criminals find it easy to manufacture and export SFFC medicines.

Trade through several intermediaries

Trade in medicines takes place mostly through one or more intermediaries, such as brokers, trading houses and agents. Activities in intermediaries may sometimes involve repackaging, relabelling and mixing. Such trade arrangements can provide better opportunities for counterfeiters to introduce illicit material into the distribution chain.

Trade through free-trade zones/free ports

Medicines are also traded through free-trade zones/free ports where control is lax or absent. In such places medicine products are sometimes relabelled in order to hide their true source and identity.

What measures should countries take to combat the problem?

Several measures need to be taken to combat the problem.

At national level governments must:

- improve the availability and affordability of medicines;
- enact deterrent legislation prohibiting the manufacture, importation, exportation, distribution and sale of SFFC medicines;
- establish or strengthen NMRA by clearly setting out its power, duties and responsibilities;
- provide the necessary human, financial and other resources to the NMRA;
- train NMRA personnel, including enforcement officers in the detection and investigation of SFFC medicines;
- foster cooperation between NMRA and other national law enforcement agencies such as police, customs, and the judiciary;
- ensure that personnel working in national medicine regulation and those involved in the detection and investigation of SFFC medicines sign conflict of interest forms;
- ensure that the medicine legislation is enforced;
- ensure that courts speedily dispose of cases involving SFFC medicines and that sentences passed by the judiciary reflect the seriousness of the problem and the offence;
- ensure that SFFC medicines are confiscated and destroyed.

National medicine regulatory authorities must:

- ensure that all medicine manufacturing, importation, exportation and distribution activities are carried out in premises approved by the NMRA, and that individuals and companies engaged have license to operate such activities;
- inspect medicine establishments regularly to ensure that they comply with national medicine regulatory requirements;

- ensure that all medicines are assessed and authorized before they are introduced to the market;
- define the ports of entry for medicines and starting materials used for the manufacture of pharmaceutical products;
- control importation of finished pharmaceutical products and starting materials by issuing import permits and inspecting consignments at points of entry as necessary
- inspect the informal market to prevent any illegal trade in medicines;
- monitor the quality of medicines on the market to detect and prevent any substandard and SFFC medicines from reaching the public;
- Work closely with national law enforcement agencies such as the police and customs officers
- inform the public about the problem of SFFC medicines and educate and advise them to buy medicines from NMRA authorized sources rather than from peddlers and hawkers or from market places and streets;
- encourage and advise consumers to report to their prescribers or physicians any lack of improvement in their health status in spite of the treatment or any adverse reactions experienced;
- foster bilateral and multilateral agreements with other countries, in particular with countries sharing common borders to prevent cross border trade and smuggling;
- seek international cooperation with organizations such as WHO, Interpol, the World Customs Organization.

Consumers should:

- buy medicines only from licensed pharmacies and medicine outlets;
- be suspicious of heavily discounted medicines;
- do not buy from peddlers or market places;
- insist to get receipts when buying medicines;
- check packaging carefully if it is properly sealed;
- check if the packaging indicates the batch number, manufacturing date, expiry date, and the manufacturer's name
- report to your health worker or doctors any lack of improvement after taking a medicine.

At international level:

Counterfeiting of medicines is now a global issue affecting all countries. Therefore in order to combat the problem effectively:

- there should be timely exchange of information on SFFC medicines between, medicine regulatory authorities, pharmaceutical manufacturers, national law enforcement officers, international organizations such as WHO, Interpol, World Custom Organization
- there should be more cooperation between all interested parties to develop harmonized measures to prevent the spread of SFFC medicines globally; cooperation would improve if all countries adopt a common definition of SFFC medicines;
- a global mechanism similar to the one used to control narcotic drugs should be created to control trade in SFFC medicines. SFFC drugs not only affect the sick and innocent consumers but also the general public and deserve more attention.