



Medicines

What encourages counterfeiting of medicines?

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Medicines are attractive for counterfeiting

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

Producing counterfeit 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 counterfeit 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 counterfeit;

Lack of political will and commitment to establish strong 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 borders, 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 counterfeit medicines.

Currently, only a few of the WHO Member States have enacted special national legislation on counterfeit medicines. Moreover, sanctions imposed

on counterfeiters are, in most cases, not deterrent.

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

Absence of or weak 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 counterfeit medicines on national market.

Weak enforcement

Enacting deterrent legislation alone will not solve the problem of counterfeit 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 counterfeit 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 counterfeit. For example, the misuse of creams containing steroids for skin bleaching and body building medicines has generated a market for counterfeit 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 counterfeit 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 counterfeit 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 counterfeit medicines is necessary in combating counterfeit medicines. Where such cooperation is lacking the NDRA may not be able to take measures against counterfeiters hence counterfeit 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 counterfeit 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.