

## KEY FACTS

- Counterfeit medicines are medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source.
- Use of counterfeit medicines can result in treatment failure or even death.
- Public confidence in health-delivery systems may be eroded following use and/or detection of counterfeit medicines.
- Both branded and generic products are subject to counterfeiting; they may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging.
- All kinds of medicines have been counterfeited, including medicines for the treatment of life-threatening conditions, expensive lifestyle medicines, and inexpensive generic versions of simple painkillers and antihistamines.

Counterfeit medicines are found everywhere in the world. They range from random mixtures of harmful toxic substances to inactive, ineffective preparations. Some contain a declared, active ingredient and look so similar to the genuine product that they deceive not only patients, but also health professionals. But in each and every case, the source of a counterfeit medicine is unknown and its content unreliable. Counterfeit medicines are always illegal. Eliminating them is a considerable public health challenge.

### Extent of the problem

Counterfeiting is greatest in those regions where medicines regulatory and enforcement systems are weakest. Thus in most industrialized countries with effective regulatory systems and market control (i.e. Australia, Canada, Japan, New Zealand, most of the European Union and the USA), incidence of counterfeit medicines is extremely low – perhaps less than 1% of market value according to the estimates of the countries concerned. But in many African countries, and in parts of Asia and Latin America, a much higher percentage of the medicines on sale may be counterfeit. For many countries of the former Soviet Union, counterfeit medicines are estimated to exceed 20% of market value. But there is huge variation between geographic regions in terms of incidence. Variation can also be significant within countries: for example, between urban and rural areas, and between cities.

### Internet counterfeiting

Medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit in over 50% of cases. (Some Internet pharmacies are legal operations, established to offer clients convenience and savings. They deliver medications from government-licensed facilities and sell only on the basis of a prescription.)

Recent examples of counterfeit medicines	
Antidiabetic traditional medicine: China, 2009	Contained 6 times normal dose of glibenclamide (used to lower blood sugar) (2 people died, 9 people hospitalized)
Metakelfin (antimalarial): Tanzania, 2009	Discovered in 40 pharmacies
Viagra & Cialis (for erectile dysfunction): Thailand, 2008	Smuggled into Thailand from an unknown source in an unknown country

Xenical (for fighting obesity): USA, 2007	Contained no active ingredient and sold via Internet sites operated outside the USA
Lipitor (for lowering cholesterol); Zyprexa for treating bipolar disorder and schizophrenia: United Kingdom, 2007	Detected in the legal supply chain

Forming an accurate picture of the extent of counterfeit medicines is difficult. Current sources of information include reports from national medicines regulatory authorities (NMRA), enforcement agencies, pharmaceutical companies and nongovernmental organizations, as well as ad hoc studies on specific geographical areas or therapeutic groups. But the variety of these sources, and the different methods used to produce reports and studies, make compiling and comparing statistics a difficult task. Moreover, studies can only give snapshots of the immediate situation. Medicines counterfeiters are extremely flexible in the methods they use to mimic products and prevent their detection. They can change these methods from day to day. Therefore, when the results of a study are released, they may already be outdated. Also, information about a case under legal investigation is sometimes only made public after the investigation has been concluded. A study that is not able to include such case information is therefore incomplete.

**Public health risks: counterfeit medicines are more dangerous than substandard medicines**

The incidence of counterfeit medicines may be less frequent than that of substandard medicines. But they pose a greater public health risk because their content can be dangerous (if, for example, they contain toxic materials) or lacking (as in the absence of active ingredient). Also, the extreme difficulty in tracing their manufacturing and distribution channels means that their circulation on markets is difficult to stop. Even a single case of a counterfeit medicine is unacceptable since it indicates that the pharmaceutical supply system in which it was detected is vulnerable. Worse, it undermines the credibility of national health and enforcement authorities.

**Contributory factors**

Medicines are needed and sought throughout the world. Paying for medicines can consume a significant proportion of individual or family income. Some patients therefore seek medicines that are sold more cheaply. These are often available from non-regulated outlets. But such outlets are more likely to sell counterfeit medicines. Patients might also purchase medicines from non-regulated outlets if, as is often the case in the rural areas of developing countries, medicines supplies at regular health facilities do not meet demand.

Counterfeiting of medicines can be very lucrative. And since many countries have not yet enacted deterrent legislation, counterfeiters often do not fear prosecution.

The growth in international trade in pharmaceutical ingredients and in medicines adds a further dimension of complexity to this issue. For example, trade through brokers and free trade zones where regulation is lax or absent (and medicines repackaged and relabelled to conceal country of origin) is increasing.

## WHO response

Stringent regulatory control and enforcement by NMRAs contributes significantly to prevention and detection of counterfeit medicines in the pharmaceutical distribution chain. WHO accordingly provides direct country and regional support for strengthening medicines regulation. But to fight counterfeit medicines effectively, a range of stakeholders, not just health professionals, is needed. In 2006, WHO therefore helped create the International Medicinal Products Anti-Counterfeiting Taskforce, commonly known as IMPACT, to bring these stakeholders together and encourage them to collaborate to protect patients from buying and taking potentially fatal, counterfeit medicines. IMPACT's current focus areas are: legislative and regulatory infrastructure; regulatory implementation; enforcement; technology; and communication.

Following discussions at the Sixty-first World Health Assembly and the 124th session of its Executive Board, WHO has established a programme to coordinate its work to combat counterfeit medicines. This programme include coordination with members of the IMPACT Taskforce and providing it with secretariat support. During the next World Health Assembly (to be held in May 2010) the topic of counterfeit medicines will be discussed, to assist the Director-General in determining WHO's future efforts to fight this unacceptable threat to public health.