World Health Organization

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Counterfeit medicines

What are counterfeit medicines?

Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals – medicines manufactured below established standards of safety, quality and efficacy. They are deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.

Until recently, the most frequently counterfeited medicines in wealthy countries were new, expensive lifestyle medicines, such as hormones, steroids and antihistamines. In developing countries the most counterfeited medicines have been those used to treat life-threatening conditions such as malaria, tuberculosis and HIV/AIDS. As the phenomenon spreads, more and more medicines are counterfeited, including expensive ones, such as anti-cancer drugs, and those highly in demand, such as antivirals.

The extent of the problem

Although it is difficult to obtain precise figures, estimates put counterfeits at more than 10% of the global medicines market. They are present in all regions but developing countries bear the brunt of the problem. An estimated 25% of the medicines consumed in developing countries are believed to be counterfeit. In some countries, the figure is thought to be as high as 50%.

The Centre for Medicines in the Public Interest, in the United States, predicts that counterfeit drug sales will reach US$ 75 billion globally in 2010, an increase of more than 90% from 2005.

Trade in these products is more prevalent in countries with weak drug regulation control and enforcement, scarcity and/or erratic supply of basic medicines, unregulated markets and unaffordable prices. However, as counterfeiting methods become more sophisticated, counterfeits are increasingly present in better-controlled markets.

Some examples:

- In late January 2006, the United States Food and Drug Administration (FDA) issued an alert about fraudulent flu remedies, including counterfeit prescription oseltamivir (Tamiflu) medication.
- The Dutch Healthcare Inspectorate warned consumers in early 2006 not to buy Tamiflu through the Internet, after counterfeit capsules were found in the Netherlands containing lactose and vitamin C, and no active substance. In the United Kingdom, officials seized 5000 packets of counterfeit Tamiflu in early 2006, estimated to be worth £500 000.
- A World Health Organization (WHO) survey of counterfeit medicine reports from 20 countries between January 1999 to October 2000 found that 60% of counterfeit medicine cases occurred in poor countries and 40% in industralized countries.
- Peru's Ministry of Health estimates that illegal sales of medicines account for 15-20% of the local market.
- A recent study in The Lancet concluded that up to 40% of products labelled as containing artusenate (the best medicine to combat malaria today) contain no active ingredients and therefore have no therapeutic benefits.

Consequences of substandard and counterfeit medicines

The regular use of substandard or counterfeit medicines can lead to therapeutic failure or drug resistance; in some

cases it can lead to death.

For example:

- During a meningitis epidemic in Niger in 1995, more than 50 000 people were inoculated with fake vaccines, received as a gift from a country which thought they were safe. The error resulted in 2500 deaths.
- The consumption of paracetamol cough syrup prepared with diethylene glycol (a toxic chemical used in antifreeze) led to 89 deaths in Haiti in 1995 and 30 infant deaths in India in 1998.
- A study conducted in WHO's South-East Asia Region in 2001 revealed that 38% of 104 antimalarial drugs on sale in pharmacies did not contain any active ingredients.
- In 1999, at least 30 people died in Cambodia after taking counterfeit antimalarials prepared with sulphadoxine-pyrimethamine (an older, less effective antimalarial) which were sold as Artusenate.

Challenges to preventing counterfeit medicines

Because of a lack of regulation and enforcement, the quality, safety and efficacy of both imported and locally manufactured medicines in many developing countries cannot be guaranteed. Smuggling and illegal importation of drugs are rife. Counterfeit drugs are not only sold in these countries but also exported or re-exported.

Some policy-makers have argued that drug regulation represents an unnecessary barrier to trade and should be reduced to a minimum. Pharmaceuticals, however, should not be considered a standard commodity, since consumers and prescribers are unable independently to assess their quality, safety and efficacy and the results can be deadly to patients.

Factors encouraging counterfeiting of drugs

The production of counterfeit drugs need not occur in large infrastructures or facilities. The majority of the counterfeiters apprehended so far carried out their activities in ordinary households, small cottage industries, or in backyards.

Counterfeiting of medicines is a hugely lucrative business due to the continued high demand for medicines and low production costs. The absence of deterrent legislation in many countries also encourages counterfeiters since there is no fear of being apprehended and prosecuted.

When prices of medicines are high and price differentials between identical products exist there is a greater incentive for the consumer to seek medicines outside the normal supply system. In many countries the official supply chain fails to reach many communities, especially in rural areas. Poverty, and the lack of an official supply chain, are major factors in creating markets for counterfeit products.

In industrialized countries, Internet-based sales of pharmaceuticals remain a major source of counterfeit medicines, threatening those who seek cheaper, stigmatized or unauthorized treatments.

Action to address substandard and counterfeit medicines

Measures for combating counterfeit medicines so far have included: actions taken by drug regulatory authorities and cooperation initiatives between different law enforcement agencies; providing simple, easily interpretable and cheap markers of authenticity; coordinating international surveillance for fake and substandard drugs; and educating patients and healthcare workers.

Legislation forms the basis for drug regulation. Medicines need to be safe, effective and of good quality in order to produce the expected therapeutic effect. Ensuring these properties requires the creation of competent national drug regulatory authorities with the necessary human and other resources to control the manufacture, importation, distribution and sale of medicines.

Legislation must be complemented with effective law enforcement. Governments need to develop strategies to reduce corruption and criminal activity and promote intersectoral cooperation between regulatory authorities, police, customs services and the judiciary to effectively control the drug market and enforce drug regulation. When that regulation is infringed, sanctions against the manufacture and distribution networks must be

commensurate to the crime.

Since the opening up of trade barriers between countries has led to an increase in counterfeiting, consistent and systematic efforts are needed at the international level. These should include the timely exchange of information and the harmonization of international measures to prevent the spread of these phenomena.

Some countries have begun to make serious efforts to address the counterfeit medicines issue. Examples include:

- Nigeria's drug regulator, the National Agency for Food, Drug Administration and Control (NAFDAC) has banned imports from 30 foreign companies. Nigeria maintains inspectors in exporting countries to ensure that drugs destined for Nigeria meet the required standards.
- Peru's Ministry of Public Health has begun information campaigns calling on Peruvian citizens to purchase medicines only at registered pharmacies.

New and innovative solutions

New solutions being developed involve technology. Some of these are low tech, such as simple colorimetric (colour) assays developed for artemisinins used successfully to identify fake artesunate antimalarials. The German Pharma Health Fund has developed the "Minilab" for analysing the authenticity of a wide range of essential drugs relatively simply and inexpensively.

Other technological solutions currently being tested are expensive. If these prove effective in the near future, the challenge will be how to extend their benefits to developing countries.

Several countries are now mandating that companies confirm the authenticity of their product by creating a "pedigree" that vouches for a medication's origin and how it has subsequently been handled.

The U.S. FDA has recommended that pharmaceutical companies start using radio frequency identification technology (RFID) as a means of better tracking drugs. Several pharmaceutical companies are experimenting with RFID and optically variable devices (OVDs) or at least using bar codes or other technologies such as web portals that can help track and authenticate the drugs.

Some companies are also testing holograms, color-shifting inks and watermarks that can help them authenticate the package and actual pills. Others are experimenting with using inks or dyes and some are already using tamper-resistant packaging tape on some of their products.

WHO action to address counterfeit medicines

WHO provides support to countries to strengthen pharmaceutical legislation, Good Manufacturing Practices (GMP), national drug regulatory capacity and performance, to promote information exchange among drug regulatory authorities and to strengthen drug procurement. WHO also works with countries to ensure that quality assurance is built into the entire drug supply chain.

Guidance materials have been prepared for countries in relation to product assessment and registration, distribution of medicines, basic tests and laboratory services. Nine GMP training workshops were held in Africa and Asia and twenty WHO GMP training modules were produced in English and translated into Spanish for Latin America. The GMP modules are regularly used for training in medicine regulation, including the registration of HIV/AIDS medicines.

In 2005, WHO's Western Pacific Regional Office set up the world's first web-based system for tracking the activities of drug counterfeiters. The Rapid Alert System communications network transmits reports on the distribution of counterfeit medicine to the relevant authorities for them to take rapid countermeasures. National health authorities and other partner agencies are linked to the system. WHO plans to extend the system to other regions in the near future.

The WHO pre-qualification of HIV/AIDS, malaria and tuberculosis medicines is also a major contribution to improving the quality of medicines for widespread conditions. It assesses products and manufacturers and provides the list of those meeting WHO standards to countries and procurement agencies to promote the purchase of good quality medicines. Given the rising demand for assistance from countries, WHO is intensifying work in

the areas of anti-counterfeiting, quality and safety control of medicines as part of its task of promoting greater access to safe, effective treatment.

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