Substandard and counterfeit medicines

What are substandard and counterfeit medicines?

Substandard medicines are products whose composition and ingredients do not meet the correct scientific specifications and which are consequently ineffective and often dangerous to the patient. Substandard products may occur as a result of negligence, human error, insufficient human and financial resources or counterfeiting.

Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals. The difference is that they are deliberately and fraudulently mislabeled 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.

In wealthier countries the most frequently counterfeited medicines are new, expensive lifestyle medicines, such as hormones, steroids and antihistamines. In developing countries the most counterfeited medicines are those used to treat life-threatening conditions such as malaria, tuberculosis and HIV/AIDS.

The extent of the problem

The United States Food and Drug Administration estimates that counterfeits make up more than 10% of the global medicines market and are present in both industrialized and developing countries. It is estimated that up to 25% of the medicines consumed in poor countries are counterfeit or substandard.

These figures place the annual earnings from the sales of counterfeit and substandard medicines at over US$ 32 billion globally.

Trade in these medicines 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, one of the most counterfeited drugs today is Viagra, which is sold extensively via the Internet in industrialized countries.

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 industrialized countries.

In April 1999, reports of 771 cases of substandard medicines had been entered into the WHO database on counterfeits, 77% of which were from developing countries. Data analysis showed that in 60% of the 325 cases an active ingredient was missing from the product.

A recent study in The Lancet concluded that up to 40% of artusenate products (the best medicine to combat resistant malaria today) contain no active ingredients and therefore have no therapeutic benefits.
In 2002, GlaxoSmithKline in the United States discovered suspect bottles containing 60 tablets of Combivir (lamivudine plus zidovudine) that actually contained another medicine, Ziagen (abacavir sulfate). The company determined that counterfeit labels for Combivir tablets were placed on two bottles of Ziagen and labels on another two bottles were suspect. Both medicines are used as part of combination regimens to treat HIV infection and can cause potentially life-threatening hypersensitivity reactions in patients taking other medicines in the combination.

**Consequences of substandard and counterfeit medicines**

At best, the regular use of substandard or counterfeit medicines leads to therapeutic failure or drug resistance; in many cases it can lead to death.

During the meningitis epidemic in Niger in 1995, over 50,000 people were inoculated with fake vaccines, received as a gift from a country which thought they were safe. The exercise resulted in 2,500 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.

Of the one million deaths that occur from malaria annually, as many as 200,000 would be avoidable if the medicines available were effective, of good quality and used correctly.

A study conducted in South-East Asia in 2001 revealed that 38% of 104 antimalarial drugs on sale in pharmacies did not contain any active ingredients and had resulted in a number of preventable deaths.

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**

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. Subsequently, smuggling and illegal importation of drugs are often rife. Substandard and counterfeit drugs are then not only sold in these countries but also exported or re-exported.

The situation is worsened by the fact that medicines exported from many industrialized countries are not regulated to the same level as those domestically consumed, while export of drugs to developing countries via free trade zones is increasing. Relabelling of products to mask details of their origin is also known to occur.

Some policy-makers now believe that drug regulation represents an unnecessary barrier to trade and should be reduced to a minimum. Pharmaceuticals, however, cannot be considered a standard commodity since consumers and prescribers are unable to assess their quality, safety and efficacy and the results can be harmful to patients’ health.

Growing international and national trade in alternative medicines, including herbal products, is also becoming more complex following rapid increases in demand. Significant quantities of herbal products are now imported by countries in Europe, North America and Asia. However, the use and production of herbal products remains largely unregulated and their safety and therapeutic value cannot always be guaranteed.

**Factors encouraging counterfeiting of drugs**

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

Counterfeiting of medicines is a hugely lucrative business due to high demand 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. Poverty, then, is one of the major factors in the production and consumption of substandard products.

National action to address substandard and counterfeit medicines

Legislation forms the basis for drug regulation. Medicines need to be safe, effective and of good quality in order to produce the desired 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.

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.

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 and appropriate exchange of information and the harmonization of measures to prevent the spread of these phenomena.

Some countries have begun to make serious efforts to address the counterfeit medicines issue. In China last year, for instance, the State Drug Administration closed 1,300 illegal factories and investigated cases of counterfeit drugs worth US$ 57million.

WHO action to address substandard and counterfeit medicines

The overall goal of WHO support has been to promote the regular availability and accessibility of affordable essential medicines of good quality. 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. CD-ROM versions of these were translated into Chinese and Japanese and distributed to 5,800 government officials and regulatory authorities staff. The GMP modules are regularly used for training in medicine regulation, including the registration of HIV/AIDS medicines.

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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