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## Counterfeit pharmaceutical products

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According to WHO, US\$ 34 billion dollars worth of medicines were counterfeit in 2001, accounting for 15% of total world output. Every country is affected and countries with weakly regulated pharmaceutical markets tend to suffer the most.

In 2001, the pharmaceutical industry invested US\$ 30 billion in research and development. R&D of new drugs is a costly, lengthy process, and is also very risky: a single new medicine normally takes more than 10 years and US\$ 800 million to develop. However, pharmaceuticals do provide solution to escalating health care costs, since they are potentially the most cost-effective means of saving life and preventing disease, minimizing the need for surgery, hospitalization, physician visits and nursing care. Counterfeit pharmaceuticals not only deny all these benefits but put people's health and even life at risk.

According to WHO, the most common counterfeits are the "look-alikes", which physically resemble the genuine drug in appearance and packaging, but which have little or no active ingredient, and may even contain harmful substances.

There are several approaches to reducing the harmful effects of counterfeit pharmaceuticals:

- Detection — inspectors should be better trained to differentiate genuine medicines from counterfeits.
- Prosecution — law enforcement agencies should be empowered.
- Execution — collaboration is needed between companies and national and international authorities.
- Penalties — these should be severe enough to serve as a deterrent.
- Education — both professionals and consumers need to be better informed and to play an active role in the fight against counterfeit pharmaceuticals.

Better communication among all parties, such as international and national regulators, the pharmaceutical industry, health care professionals and customers, is key to combating counterfeit drugs; regulatory bodies should be at the centre of the communication network.

There are no “quality counterfeits”. All are unsafe and ineffective and can even be life-threatening. Through CARE, which stands for communication, alliance, responsibility and elimination, from all involved parties, the challenge of counterfeits can be dealt with.

## **The fight against counterfeit drugs in the Russian Federation**

### **Dr Alexander Toporkov, Russian Federation**

In recent years, the Russian Federation has faced a marked increase in counterfeit medicines. The data suggest that two-thirds of these fake medicines were made within the country. Most of the fake medicines were found by departments in the monitoring and approval system during quality control and medicine certification operations. In most cases, the counterfeits were discovered during the process of ensuring that their quality complied with the requirements of regulatory documentation, such as description, labelling, authentication and quality.

The most commonly counterfeited drugs are the antibacterials. Cases have been found where the fake medicines displayed the same serial number as the genuine ones.

The reasons behind the increase in fake medicines in the Russian Federation are believed to be:

- shortcomings in the current legislation governing the trade in medicines;
- a large number of intermediary distributors in the pharmaceutical market;
- the gulf between the cost of drugs and the purchasing power of the public;
- inadequate interdepartmental coordination in the fight against fake products;
- easy availability of sophisticated modern equipment for production and packaging of medicines;
- a large number of enterprises that do not conform to GMP.

The problem of counterfeit medicines also leads to economic problems, such as direct losses for Russian and foreign producers, the costs of combating the fake medicines and protecting trade marks, overall costs to the health sector caused by inappropriate treatments, and unpaid taxes and duties.

Because of the inadequacy of the existing legislation, an amendment is being drafted to the Federal Law on Medicines, to introduce the concept of counterfeit medicines, to ban their preparation, production, sale and import into the Russian Federation, and to criminalize their production, advertising, preparation, packaging, labelling, acquisition, storage, or transport for the purposes of sale. The amendment also covers medicines accompanied by false information concerning contents and/or producer.

In August 2001, the Russian Ministry of Health set up a Commission to combat the trade in fake medicines, including personnel from the

Customs Committee, the Ministry of the Interior, the Federal Security Service, the Ministry of Industry, Science and Technology, the Prosecutor-General and the Supreme Court.

In December 2001, the Russian Ministry of Health set up the Pharmaceutical Inspectorate to:

- organize inspection checks;
- inform law enforcement and monitoring agencies of violations uncovered;
- collaborate on drafting regulations and laws dealing with quality control;
- set up a database on those parties involved in the trade in medicines for information and analysis.

### **Counterfeit medicines** **Mr Steve Howells, Australia**

In Australia, counterfeiting is a crime. Goods are defined as counterfeit if the label or presentation of the goods, or any document or record relating to the goods or their manufacture, or any advertisement for the goods, contains a false representation of any of the following:

- the identity or name of the goods;
- the formulation, composition or design specification of the goods or of any ingredient or component of them;
- the presence or absence of any ingredient or component of the goods;
- the strength or size of the goods (other than the size of any pack in which the goods are contained);
- the strength or size of any ingredient or component of the goods;
- the sponsor, source, manufacturer or place of manufacture of the goods.

The above law applies to all therapeutic goods including medicines, such as prescription drugs, over-the-counter drugs, herbal medicines, vitamins, minerals, traditional medicines, sunscreens and homoeopathic medicines, and devices such as artificial organs, prosthetic devices, surgical instruments, bandages and condoms. It also applies to ingredients and components used in the manufacture of medicines and devices respectively. Goods for use in humans and animals are treated in the same way.

Counterfeiting can also involve substituting a cheaper unapproved product, switching labels, misrepresenting ingredients, source, place of manufacture, dosage, etc. in documentation, and false trial and/or test data. The import, export, manufacture and supply of counterfeit goods are all treated as criminal offences. All counterfeit imports and exports can be seized and destroyed without prosecution in Australia.

The above offences carry a penalty of AUS\$ 55 000 fine and/or 5 years of imprisonment if committed by an individual, and AUS\$ 275 000 fine if committed by a corporation.

A number of specific measures are needed to combat counterfeiting:

- adoption of the WHO guidelines;
- making counterfeiting a specific crime;
- an effective licensing and registration system;
- strengthened export controls;
- use of criminal investigators to carry out investigations;
- enhanced cooperation between local police, customs and health agencies;
- increased cooperation of drug regulatory authorities and agencies in different countries;
- support from the pharmaceutical industry.

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## Recommendations

1. Governments should acknowledge the problem of counterfeit drugs by developing national policies and providing a comprehensive legal framework to regulate trading of counterfeit drugs as a criminal offence.
2. Governments should adopt WHO guidelines for the development of measures to combat counterfeit drugs.
3. Governments of exporting countries should have a system of control to prevent the export of counterfeit drugs.
4. Drug regulatory authorities should establish a working relationship with national (police, customs) and international (Interpol, World Customs Organization) law enforcement agencies.
5. Drug regulatory authorities should establish an effective registration system to include the licensing of manufacturers, wholesalers, and retail outlets.
6. Drug regulatory authorities should seek to cooperate with the drug industry in the exchange of information on counterfeit drugs, and to promote reporting of counterfeit drugs to WHO.
7. WHO should strengthen the existing anti-counterfeit liaison officers to promote exchange of information on counterfeit drugs amongst and between regulatory authorities and WHO.
8. WHO should encourage and support Member States to develop and implement national measures for combating counterfeit drugs.
9. WHO should organize meetings to enhance international communication on counterfeit problems and encourage and assist regulatory authorities in the delivery of public awareness programmes on the dangers of counterfeit drugs.
10. Progress should be reported back to the ICDRA.