

## WHO News

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# Counterfeit medicines: An intent to deceive<sup>1</sup>

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It has been said that imitation is the highest form of flattery. However, we can do without this type of flattery if it harms our health. ‘Brand name’ goods such as watches and clothes have always attracted the attention of unscrupulous counterfeiters everywhere in the world. Unfortunately, this menace has also spread to the world of medicines, putting hundreds and thousands of unsuspecting lives into serious danger. Counterfeiting is deceptive and immoral in any field. But in healthcare, it is criminal and simply unacceptable.

### **What are counterfeit medicines?**

According to WHO, a counterfeit medicine is a product which is ‘*deliberately and fraudulently mislabelled with respect to identity and/or source*’. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging. It is important to make a distinction between counterfeit medicines and other kinds of substandard medicines: all counterfeit medicines are substandard because they are manufactured and distributed outside of regulatory control and their composition is unpredictable. On the other hand, not all substandard medicines are counterfeit because not all of them have been ‘*deliberately and fraudulently mislabelled*’. Experience has shown that there are ‘many kinds’ of counterfeit medicines. Counterfeiters have targeted well known as well as unbranded products, expensive as well as inexpensive products. They have even produced fake medicines that do not refer to any existing brand or manufacturer.

### **What are the consequences of counterfeit medicines?**

Therapeutic failures and adverse effects would be the more serious consequences. In fact many cases of counterfeiting have been uncovered while investigating therapeutic failure or adverse events observed in patients. But a serious if not fatal consequence is the erosion of confidence in health-care systems.

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### **Where do we find counterfeit medicines?**

Everywhere. No country is outside the counterfeiters' reach, the problem is truly global. Counterfeit medicines are increasingly detected in European and North-American countries. This suggests that even countries with advanced regulatory systems are seriously challenged by this menace. Nor are some medicines free from this disgrace; if widely used medicines such as atorvastatin and paracetamol are counterfeited, so are other, less commonly used products such as growth hormone, paclitaxel and fil-gastrim. Stated differently, counterfeits can surface in community pharmacies and in hospitals alike.

Nobody knows the precise extent of the problem. Counterfeits are difficult to detect, investigate or quantify. Rough estimates, mainly based on unpublished reports, suggest that up to 10% of the medicines circulating in the world could be counterfeit. It is very likely that this estimate is not a realistic description of the situation of the best regulated countries of the world. Yet, even a few dozen cases in a year mean many thousands of tablets and ampoules and therefore many thousands of patients at risk!

### **Who are the counterfeiters?**

Counterfeiting medicines has attracted organized crime, but it also requires the cooperation of people with some experience in pharmaceutical manufacturing and distribution. In addition to organized crime, there are small-scale counterfeiting activities. And individuals indulge in it as well, as in the case of Robert Courtney, a Kansas City pharmacist who, in ten years, accumulated at least US\$19 million by diluting injections, often prepared for patients he personally knew. He got a 30-year prison sentence.

Counterfeiting is 'easy business' because:

- it is relatively easy to hide and smuggle medicines: very few countries have customs control that is specialized in detecting counterfeit medicines;
- most users are not able to distinguish between real and counterfeit;
- manufacturing bad quality medicines does not require huge investment and the equipment is easy to move from one 'counterfeit' site to another;
- in many countries, regulatory and control systems, especially oversight on distribution channels, are ineffective;
- in addition, in most countries, punishment is not sufficiently strong to deter criminals.

And governments face considerable challenges in fighting the menace because of:

- a lack of willingness to recognize the existence or the seriousness of the problem;
- inadequate legal framework and ineffective punishment: counterfeiting medicines is not properly defined and is dealt with in the same way as all other types of counterfeiting;
- weak administrative and coordination measures;
- ineffective control on pharmaceutical manufacturing, importation and, especially, distribution.

Additional factors include national drug policies that prioritize export activities over compliance with good manufacturing practices; ineffective collaboration among authorities and institutions involved in regulation, control, investigation and prosecution (e.g. Drug regulatory authorities, police, customs and the judiciary); an extremely fragmented distribution channel that increases the opportunities for counterfeiters to infiltrate the system; wide price gaps or extremely high prices in countries that cause patients to 'wander' in search of 'affordable' versions of the medicines; internet vending of medicines; and third-party manufacturing, which, if not properly and carefully organized, may lead to unauthorized and substandard use of manufacturing techniques and packaging materials.

## How to protect public health?

Combating counterfeit medicines requires collaboration, at national, regional and international levels involving all stakeholders of the public sector and the civil society including health professionals, patients, manufacturers, distributors, as well as communication professionals and the media. But the first step is to sensitize and obtain the commitment of law-makers to introduce adequate legislative measures that clearly define and recognize counterfeiting of medicines as a crime that is different and far more serious than the counterfeiting of other kinds of goods.

Efficient coordination mechanisms should be put in place for rapid and effective anti-counterfeit measures without bureaucratic delay. While regulations and controls should not unnecessarily hinder the exportation of medicines, it is necessary to ensure that both exporting and importing countries can apply measures that permit to effectively identify the actual origin of exported medicines. Liberalization and intensification of international trade offer opportunities for trading in medicines of unclear origin, including counterfeits. It is necessary that national authorities improve border control and develop appropriate international collaboration and exchange of information through international legal and administrative agreements. Essential stakeholders in these efforts should include Interpol, the Organisation for Economic Co-operation and Development, the World Customs Organization, the World Intellectual Property Organization, the World Trade Organization, and the World Health Organization.

Pharmaceutical manufacturers and their associations are also key players in combating counterfeit medicines. In the past, many companies kept quiet on the cases that were detected, probably fearing negative publicity for the company products. However, this attitude has now changed. Industry has an important role in providing information as well as in developing technologies that help detect and deter the manufacture of counterfeit medicines. In a similar vein, distributors, wholesalers, importers and exporters should develop and effectively implement business practices that make the distribution chain impermeable to counterfeits and open to appropriate verification by national authorities. Purchasing organizations and NGOs should similarly develop appropriate procurement procedures. Other players in this important battle are the health professionals; nurses and pharmacists should stay vigilant to the presence of counterfeits and report suspicious products. Similarly, physicians should rule out counterfeits as a possible cause of adverse reactions or therapeutic failure. To complete the cycle of protection, the public must do their bit as well: patients must report to their pharmacists and doctors if they sense any irregularity with their medication, if they experience a side effect or a decrease in beneficial effect.

The International Medical Product Anti-Counterfeiting Taskforce, IMPACT was established by WHO with the aim of bringing together all key stakeholders at the international, regional and national level, to effectively combat counterfeit medicines. The Declaration of Rome describes the background and captures the remit of the task force.

### Declaration of Rome

18 Feb 2006

The participants of the WHO International Conference  
'Combating Counterfeit Drugs: Building Effective International Collaboration',  
gathered in Rome on 18 February 2006

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1. Counterfeiting medicines, including the entire range of activities from manufacturing to providing them to patients, is a vile and serious criminal offence that puts human lives at risk and undermines the credibility of health systems.

2. Because of its direct impact on health, counterfeiting medicines should be combated and punished accordingly.
3. Combating counterfeit medicines requires the coordinated effort of all the different public and private stakeholders that are affected and are competent for addressing the different aspects of the problem.
4. Counterfeiting medicines is widespread and has escalated to such an extent that effective coordination and cooperation at the international level are necessary for regional and national strategies to be more effective.
5. National, regional and international strategies aimed at combating counterfeit medicines should be based on:
  - a) political will, adequate legal framework, and implementation commensurate to the impact of this type of counterfeiting on public health and providing the necessary tools for a coordinated and effective law enforcement,
  - b) inter-sectoral coordination based on written procedures, clearly defined roles, adequate resources, and effective administrative and operational tools,
  - c) creating an awareness about the severity of the problem among all stakeholders and providing information to all levels of the health system and the public,
  - d) development of technical competence and skills in all required areas,
  - e) appropriate mechanisms for ensuring vigilance and input from healthcare professionals and the public.
6. The WHO should lead the establishment of an International Medical Products Anti-Counterfeiting Taskforce (IMPACT) of governmental, non-governmental and international institutions aimed at:
  - a) raising awareness among international organizations and other stakeholders at the international level in order to improve cooperation in combating counterfeit medicines, taking into account its global dimensions,
  - b) raising awareness among national authorities and decision-makers and calling for effective legislative measures in order to combat counterfeit medicines,
  - c) establishing effective exchange of information and providing assistance on specific issues that concern combating counterfeit medicines,
  - d) developing technical and administrative tools to support the establishment or strengthening of international, regional and national strategies,
  - e) encouraging coordination among different anti-counterfeiting initiatives.

The IMPACT shall function on the basis of existing structures/institutions and will in the long term explore further mechanisms, including an international convention, for strengthening international action against counterfeit medicines.