COUNTERFEIT DRUGS KILL!

Counterfeits have harmful effects on patients' health and can kill

Counterfeits frustrate efforts to deal with high burdens of disease

Counterfeits undermine health care systems

Increased international collaboration is essential to defeat counterfeiting

Combating counterfeiters requires acting at the same time on legislation, regulations, enforcement, technology and communication strategies

World Health Organization

Updated May 2008

IMPACT
International Medical Products Anti-Counterfeiting Taskforce

IMPACT
International Medical Products Anti-Counterfeiting Taskforce

What are counterfeit medicines?

Counterfeit medicines are deliberately and fraudulently mislabelled with respect to identity or source: their quality is unpredictable as they may contain the wrong amount of active ingredients, wrong ingredients or no active ingredients. In all cases counterfeit medicines are manufactured in clandestine laboratories with no possibility of control.

Counterfeiting of medicines occurs both with branded and generic products. Counterfeiting has also been discovered in relation to medical devices. It has been found that counterfeiters copy or imitate existing products, but they also manufacture products which they have invented, and are not normally available.

A global public health risk

Counterfeit medicines represent an enormous public health challenge. Anyone, anywhere in the world, can come across medicines seemingly packaged in the right way but which do not contain the correct ingredients and, in the worst-case scenario, may be filled with highly toxic substances. In some countries, this is a rare occurrence, in others, it is an everyday reality.

Counterfeit medicines range from random mixtures of harmful toxic substances to inactive, useless preparations. Occasionally, there can be fakes that do contain the declared active ingredient and look so similar to the genuine product to deceive health professionals and patients. In all cases counterfeits content is unreliable, their source is unknown and, by definition, always illegal.

Any kind of product can be and has been counterfeited: expensive lifestyle and anticancer medicines, antibiotics, medicines for hypertension and cholesterol-lowering medicines, hormones, steroids and inexpensive generic versions of simple pain killers and antihistamines, blood glucose test strips and condoms. In developing countries the most disturbing issue is the common availability of counterfeited medicines for the treatment of life-threatening conditions such as malaria, tuberculosis and HIV and AIDS.

Counterfeit medicines can harm and kill

The use of substandard or counterfeit medicines can lead to therapeutic failure or drug resistance. In some cases, it can lead to death. In 2004, fake medicines led to a trail of death in Argentina. In 2006 more than 100 patients have been killed in Panama by medicines manufactured with counterfeit glycerin.

KEY FACTORS THAT MAKE COUNTERFEITING POSSIBLE

Easy money is the main driver for counterfeiters. Manufacturing costs are very low if no quality and safety standards are respected.

Inadequate legislation, regulations and enforcement result in supply systems vulnerable to counterfeit products and extremely low capacity to uncover and punish counterfeiters;

Ineffective cooperation among stakeholders: health authorities, customs, police, industry and trade need to establish effective cooperation and exchange of information in order to detect and stop counterfeiters;

Lack of awareness: ignorance of the risks of counterfeit medicines among health professionals and patients hinders detection and reporting, even when patients experience treatment failure or adverse reactions;

Costs of medical products: the costs of legitimate medicines, both original and generic, may be too high for patients, causing them to seek high-risk "bargains" in unregulated markets (e.g., street markets or the Internet);

Lack of political will: in some countries authorities are not prepared to recognize the existence of the problem or to pursue counterfeiters if there is inadequate appreciation of the public health value of medical products compared to considerations of export interests;

Transactions involving many intermediaries increase opportunities for counterfeiters to infiltrate the regulated distribution system;

Expansion and deregulation of trade offer greater opportunities, especially through 'free trade zones', to introduce fake products into official channels.

WHAT PRIORITY ACTION SHOULD COUNTRIES TAKE?

Strengthen **legislation** ensuring that counterfeiting medical products is a crime and that punishment is commensurate to the consequences that it has on personal health and on the credibility of national health care delivery systems.

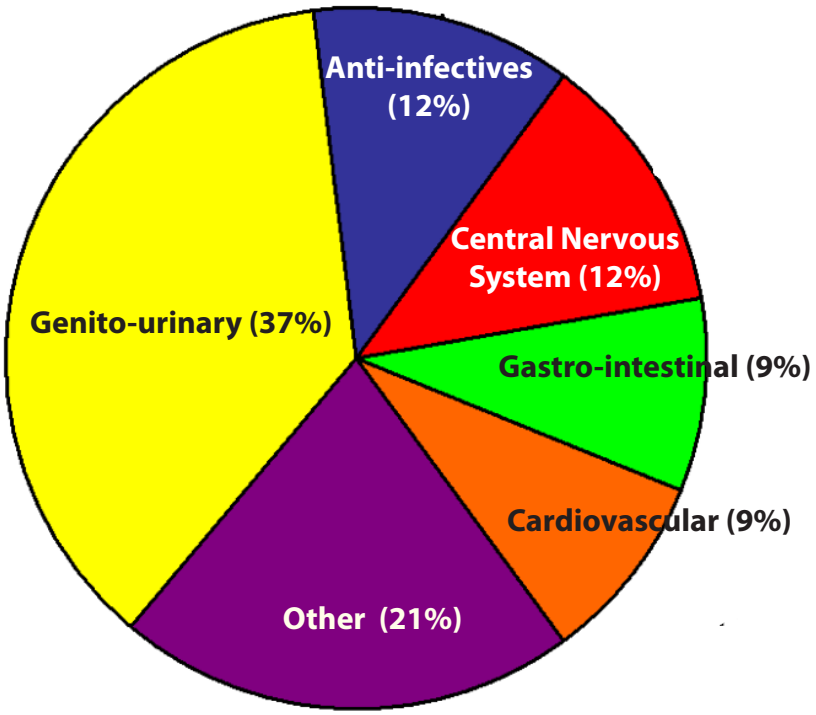
Strengthen **regulatory oversight** ensuring that all manufacturers, importers, exporters, distributors and retailers comply with the appropriate requirements that are necessary for a secure distribution chain for all medical products.

Improve **collaboration among governmental entities** (such as health, police, customs, local administrative units, judiciary) that need to work together in order to effectively combat counterfeiters.

Develop a **communication strategy** to ensure that health professionals, the general public and the media are aware of the dangers associated with counterfeit medicines.

Veronica Diaz was a healthy 22-year old woman, living in Viedma, Argentina, who had mild anaemia and was given injections of an iron-based preparation. In December 2004, she became very sick and died of liver failure after receiving the seventh of a 10-injection treatment. The medicines authority of Argentina, ANMAT, determined that she had been given a highly toxic counterfeit. Authorities were unable to determine the source of the counterfeit product due to falsified paper work. While most of the counterfeit production throughout Argentina was recovered and four people were prosecuted, the highly fragmented distribution system prevented the recall from being 100% successful. In May 2005 another woman died and a 22-year old pregnant woman was injected with the same counterfeit. She survived but gave birth to a 26 week premature baby. To date, Argentinean law does not consider counterfeiting medicines per se a crime.

Reports of counterfeit medicines by therapeutic category 2007 - Total number of cases: 1513



One case reflects at least one production lot, e.g. thousands of tablets, capsules, or other forms. Several cases included multiple therapeutic categories (only the most frequent category is included in the chart). Available data underestimate reality, especially in poorer areas where detection and reporting are extremely weak.

Source: PSI*

*: PSI - Pharmaceutical Security Institute http://www.psi-inc.org/index.cfm

The size of the problem

The extent of counterfeiting is impossible to quantify. Currently, the sources of information available include reports from nongovernmental organizations, pharmaceutical companies, national medicine regulatory and enforcement authorities, ad hoc studies on specific geographical areas or therapeutic groups, and occasional surveys. These sources of information emphasize the complexity of making estimations.

Reports from developing countries, especially in sub-Saharan Africa, are extremely rare and do not permit to draw a realistic picture of a situation that is generally considered to be highly unsatisfactory because of the weakness of regulatory and enforcement systems and the widespread presence of unregulated distribution and retail facilities. Apart from the huge differences between regions, variations can also be dramatic within countries, i.e. city versus rural areas, city versus city. Counterfeiting is greatest in those regions where the regulatory and legal oversight is weakest. This situation puts rural and the poorer segments of the population at a particular disadvantage.

In summary:

» Most industrialized countries with effective regulatory systems and market control (e.g. USA, most of EU, Australia, Canada, Japan, New Zealand) have an extremely low proportion, i.e. significantly less than 1% of the market value

» Many countries in Africa and parts of Asia and Latin America have areas where more than 30% of the medicines on sale can be counterfeit;

» In many of the countries of the former Soviet Union the proportion of counterfeit medicines is above 20% of market value

» Medicines purchased over the Internet from illegal sites that conceal their physical address are counterfeit in over 50% of cases.

These estimated ranges do not aim at providing an exact figure but rather an indication of the different possible levels of prevalence in different parts of the world.

Even one single case of counterfeit medicine is not acceptable because, in addition to putting patients at risk and undermining the public confidence in their medicines, it also betrays the vulnerability of the pharmaceutical supply system and jeopardizes the credibility of national authorities (health and enforcement alike).

Counterfeiting grows more sophisticated

Counterfeit medicines are increasingly present even in the best controlled markets, as shown in the following examples:

• In the past three years, here have been nine recalls of counterfeit medicines which had reached pharmacy and patient levels in the UK.

• The United States Food and Drug Administration has opened over 50 cases of counterfeit medical products in 2006

• April 2007: the United States Food and Drug Administration issued an alert about a counterfeit antiretroviral medicine.

• 2006: The Dutch Healthcare Inspectorate warned consumers not to buy oseltamivir, a flu medication, through the Internet, after counterfeit capsules were found in the Netherlands containing lactose and vitamin C, and no active substance.

Fake **medical devices** (i.e. medical products other than medicines ranging from contact lenses to condoms, heart valves, surgical instruments and syringes) are also increasingly present:

- 2007, UK: 10 reported cases of counterfeit condoms, packaged to a high standard difficult to distinguish from the genuine article, deficient in terms of quality and performance.

- 2006, USA: counterfeit blood glucose test strips used by people with diabetes to measure their blood glucose.

• 2004: In France, counterfeit contact lenses were detected by the regulatory authorities after receiving complaints from patients.

Internet sales

In many countries, Internet-based sales of medicines are a major source of counterfeits, threatening those who seek cheaper, stigmatized or unauthorized treatments.

Some Internet pharmacies are legal operations, set up to offer clients convenience and savings. They require patient prescriptions and deliver medications from government licensed facilities. Illegal Internet pharmacies conceal their real identity, are operated internationally, sell medications without prescriptions, and deliver products with unknown and unpredictable origins or history.

Key challenges to halting counterfeit medical products

Counterfeiting medical products is a crime carried out using deception and other techniques typical of organized crime. Health authorities are not equipped to adequately address this situation alone.

In order to combat counterfeiters, it is necessary to develop and establish appropriate mechanisms of effective collaboration between health authorities, police, customs, the judiciary, manufacturers, wholesalers, retailers, health professionals and patients.

Some policy-makers have argued that medicine regulation represents an unnecessary barrier to trade and should be reduced to a minimum. Medical products, however, are not a standard commodity. Consumers and prescribers are unable to assess their quality, safety and efficacy independently, and ineffective regulatory oversight can have deadly consequences for patients.

The production of counterfeit medicines does not require large infrastructures or facilities. Most of the counterfeiters apprehended so far carried out their activities in ordinary homes, small 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.

In many countries people have inadequate access to health services,


Medicines, including antibiotics and antimalarials on sale on market stalls

reliable pharmaceutical supply, health insurance or social security systems. In these situations, far too common in poor areas of developing countries, people have to pay out of pocket for their medicines and therefore seek cheaper sources. Counterfeiters take advantage of this and abuse populations in real need by providing fake medicines.

WHO leads the global effort to combat counterfeit medicines

In order to mobilize awareness and action in the fight against fake medicines, in February 2006, WHO created the first global initiative, known as the International Medical Products Anti-Counterfeiting Taskforce (IMPACT).IMPACT is comprised of all 193 WHO Member States on a voluntary basis and includes international organizations, enforcement agencies, national medicine regulatory authorities, customs and police organizations, nongovernmental organizations, associations representing pharmaceutical manufacturers and wholesalers, health professionals and patients' groups. These groups have joined to improve coordination and harmonization across and between countries so that eventually the production, trading and selling of fake medicines will cease.

Who is supporting the work of IMPACT?

The World Health Organization spearheaded the creation of the WHO IMPACT coalition, which is supported by national medicines regulatory authorities and Ministries of Health of WHO Member States and a number of other stakeholders. These include: Interpol, Organisation for Economic Cooperation and Development, World Customs Organization, World Intellectual Property Organization, World Trade Organization, European Commission, Council of Europe, International Federation of Pharmaceutical Manufacturers and Associations, European Generic Medicines Association, World Self-Medication Industry, Asociación Latinoamericana de Industrias Farmacéuticas, Commonwealth Secretariat, ASEAN Secretariat, International Federation of Pharmaceutical Wholesalers, European Association of Pharmaceutical Full-line Wholesalers, International Pharmaceutical Federation, International Council of Nurses, World Medical Association, International Alliance of Patients' Organizations, ReMed, Pharmaciens Sans Frontières, the United States Pharmacopeia, German Pharma Health Fund.

To accomplish this mandate, IMPACT focuses on the following five key areas:

Legislative and regulatory infrastructure. In most countries, national legislation is often not equipped to deal with the extremely serious consequences of counterfeit medicines and penalties for counterfeiters are too light to act as deterrents. Stronger legislation clearly identifying counterfeiting medical products as a crime will help to empower regulators, police, customs officials and the judiciary. IMPACT stakeholders have reviewed existing legislative instruments and have developed **"Principles and Elements for National Legislation against Counterfeit Medical Products"** covering administrative, civil and penal aspects of legislation aimed at combating counterfeit medical products. This document aims to assist Member States in establishing, complementing or updating national/regional legislation or regulation regarding counterfeit medical products. It is available at http://www.who.int/entity/impact/events/FinalPrinciplesforLegislation.pdf. The text will be disseminated and promoted during 2008 in order to provide support to countries that want to strengthen their legislative infrastructure.

Regulatory implementation. IMPACT stakeholders are working at ways to help national authorities to take action and implement legislative and regulatory measures on counterfeit medical products. These include a broad variety of activities such as guidance for improving control on importation, exportation and distribution of medical products, tools to assess national situations and needs, model approaches to procedures to managing cases of suspected counterfeit products, models for establishing effective exchange of information at national and international levels, and for establishing effective coordination among health authorities, police, customs, judiciary, manufacturers, distributors, health professionals to ensure proper detection, regulation, control, investigation and prosecution. IMPACT will develop projects to help countries with weak regulatory systems to strengthen them by improving collaboration and drawing from the experience, capacity and resources of all IMPACT stakeholders.

Enforcement. By working with INTERPOL, World Customs Organization, and a network of enforcement officers, the Permanent Forum on International Pharmaceutical Crime, IMPACT aims at improving contact and mutual understanding among enforcement officials of different countries in order to improve coordination of operations and exchange of information. IMPACT is also a tool for enforcement officers to establish communication with health authorities and other stakeholders. A guide to investigating counterfeiting of medical products and other pharmaceutical crimes has been prepared for IMPACT by the Permanent Forum on International Pharmaceutical Crime. The guide will be used in courses for the training of regulatory and enforcement officers. The two complementary goals that IMPACT wants to pursue with its training courses are: to provide training and to contribute to creating the conditions for

Combating counterfeit medical products entails complex operations based on effective collaboration between health and enforcement authorities

improved collaboration between health and enforcement authorities in this very specific area. Building on the work done by the Council of Europe's Ad hoc Group on Counterfeit Medicines, IMPACT is also developing a "Model for a Network of Single Points of Contact (SPOC)" which aims at facilitating operational collaboration at the international level as well as to streamline collaboration among the different national institutions and other stakeholders involved in investigating and taking proper timely action when confronted with a case of counterfeit medical product.

WHO, INTERPOL and the Association of Southeast Asian Nations Secretariat have launched a collaborative project for regulatory and enforcement authorities of all countries in the Mekong subregion: Cambodia, China, Lao People's Democratic Republic, Myanmar, Thailand and Vietnam. The project, based on previous experience*, aims to disrupt the manufacture and trade of counterfeit antimalarial agents and antibiotics through intensified cross-border collaboration.

Technology

IMPACT is helping to disseminate information useful for assessing technologies aimed to prevent, deter or detect counterfeit medicinal products. This assessment takes into account: a) cost; b) scalability; c) specific country needs and situations; d) feasibility; and e) regulatory implications. This work has lead to the following conclusions:

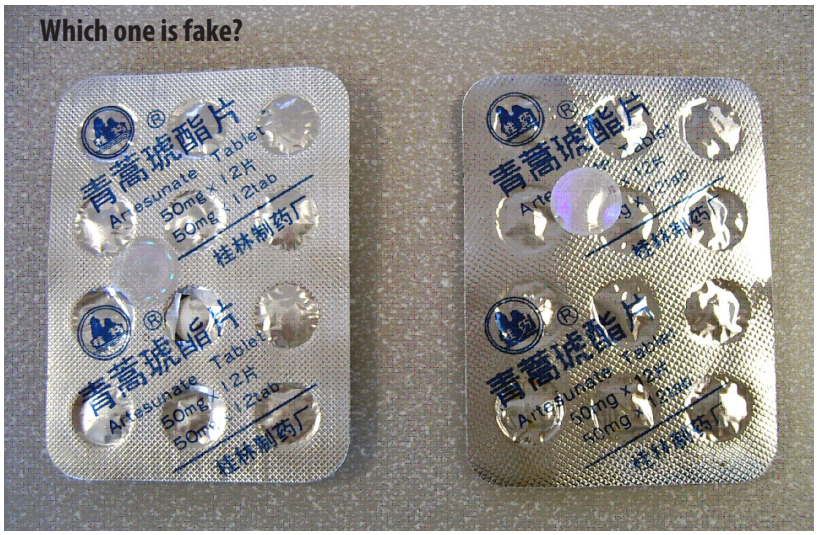
- There is no "worldwide" applicable technology, different approaches are needed.
- In developing countries the priority is to strengthen the capacity to tackle the informal trade of medicines such as street markets, smuggling and other unregulated or illegal activities.
- Countries should implement technologies appropriate to their situation and prefer those that are compatible across borders.
- Although it has been proposed as a promising solution, there are multiple weaknesses in radio-frequency identification (RFID) (including cost, privacy concerns, logistics throughout the distribution system, etc.). IMPACT consensus is that full implementation of RFID can only be envisaged in a distant future; as a consequence, the most realistic alternative to enable tracking and tracing medical products along the supply chain is the use of two dimensional barcode labels.
- The working group's view is that authentication of medicines should only go as far as the pharmacist and that the burden of verifying that a product is authentic must not fall on patients.

Communication

IMPACT has drawn up a communication strategy for creating awareness of the risks created by counterfeit medical products in the supply systems, supporting policy objectives and increasing commitment of those who can influence change. Model materials have been prepared to create awareness among, and foster cooperation of, health professionals. Other materials aimed at enforcement officers are being developed.

IMPACT is assisting member states to estimate the prevalence of counterfeit medical products and strengthening international information networks to exchange information and issue alerts from country to country. Increased public information is essential for patients, dispensers and doctors, who have a right to know if there are suspect goods on the market, but must also contribute to detecting counterfeits by reporting and helping to investigate suspicious cases. Special initiatives are being prepared to make Internet users aware of the risks they run when purchasing medicines from unknown sources and to alert and inform people in extremely disadvantaged areas. IMPACT's vision is that all counterfeit medical products will be eradicated from the supply chain by 2015. A communications campaign is required to create awareness and increase commitment from those who can influence change across the medicines supply chain. Different levels of engagement are required from the various stakeholders. This entails addressing, with specific strategies and goals, government institutions, industry (manufacturers and wholesalers), health-care professionals, patients and the media. IMPACT is also working at extending to all regions the availability of the web-based Rapid Alert System developed by WHO's Regional Office for the Western Pacific.

* Newton PN et al. A collaborative epidemiological investigation into the criminal fake artesunate trade in south-east Asia. PLoS Medicine, 2008, http://medicine.plosjournals.org/perlserv/?request=getdocument&doi=10.1371/journal.pmed.0050032



DECLARATION OF ROME

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

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 health-care professionals and the public.

6. The WHO should lead the establishment of an International Medical Products Anti-Counterfeiting Taskforce (IMPACT) of governmental, nongovernmental 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.

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.

IMPACT Contacts

Chair	Dr Carissa Etienne, Assistant Director-General, Health Systems and Services, WHO etiennec@who.int
Vice-Chairs	Prof Dora N. Akunyili, Director General, National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria dnakunyili@yahoo.com
	Ms Ruth Lee, Health Sciences Authority, Singapore, and Member of the Permanent Forum on International Pharmaceutical Crime ruth_lee@hsa.gov.sg
Chair of Working Group on Legislative and Regulatory Infrastructure	Dr Konstantin Keller, Federal Ministry of Health, Germany konstantin.keller@bmg.bund.de
Chair of Working Group on Regulatory Implementation	Dr Ilisa Bernstein, Director of Pharmacy Affairs, Food and Drug Administration, USA Ilisa.Bernstein@fda.hhs.gov
Co-Chairs of Working Group on Enforcement	Ms Aline Plançon, INTERPOL a.plancon@interpol.int
	Mr Eric McIntosh, Therapeutic Goods Administration, Australia Eric.McIntosh@health.gov.au
Chair of Working Group on Technology	Dr Harvey Bale, Director General, International Federation of Pharmaceutical Manufacturers and Associations, IFPMA h.bale@ifpma.org
Chair of Working Group on Communication	Mr Ton Hoek, Secretary-General, International Pharmaceutical Federation, FIP hoek@fip.org
Executive Secretary	Dr Valerio Reggi, Coordinator, Medicines Regulatory Support, Department of Technical Cooperation for Essential Drugs and Traditional Medicine, WHO reggiv@who.int

World Health Organization

IMPACT
International Medical Products Anti-Counterfeiting Taskforce