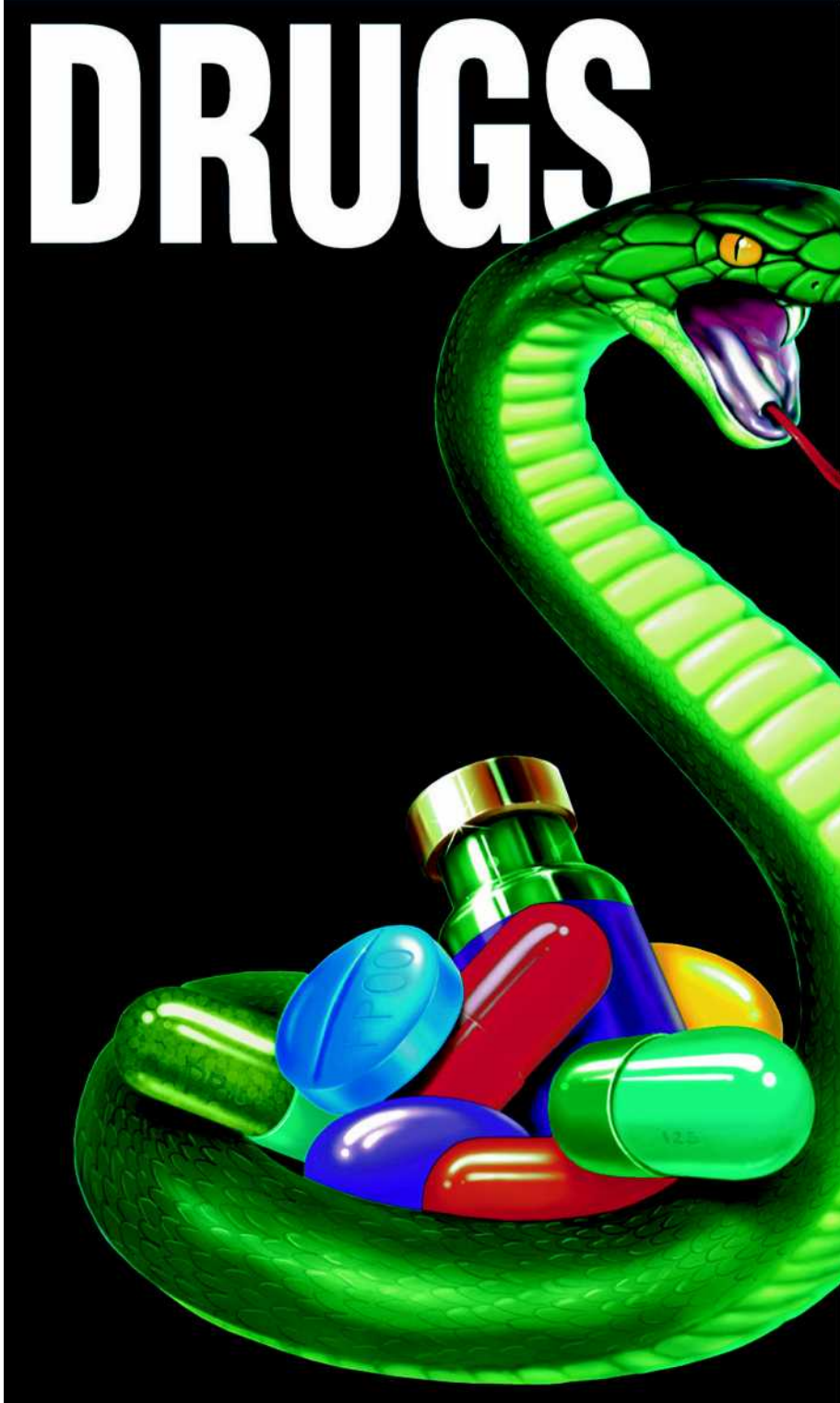


# COUNTERFEIT DRUGS KILL!



Counterfeits have harmful effects on patients' health and can kill

Counterfeits frustrate efforts to deal with high burdens of disease

Counterfeits undermine the credibility of health care systems

Increased international collaboration is essential to beat counterfeiting



World Health  
Organization

**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 secretly with no possibility of control.

Counterfeiting occurs both with branded and generic products. It has been found that counterfeiters copy or imitate existing products but they also manufacture products that are completely invented.

## A global public health crisis

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 «high quality» fakes that do contain the declared active ingredient. In all cases, contents of counterfeits are unreliable because their source is unknown and, by definition, always illegal. Fake drugs can cause harm to patients and sometimes lead to death.

Any kind of product can be and has been counterfeited: expensive lifestyle and anticancer medicines, antibiotics, medicines for hypertension and cholesterol-lowering drugs, hormones, steroids and inexpensive generic versions of simple pain killers and antihistamines. 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 regular 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.

## KEY FACTORS THAT MAKE COUNTERFEITING POSSIBLE

**Inadequate legislation and enforcement:** The main reason for counterfeiting medical products is the huge sums of money that can be made because of the low manufacturing costs. However, in many countries legislation or enforcement are inadequate and counterfeiters face extremely low risks of being punished.

**Insufficient penal sanctions** make counterfeiting attractive for criminals.

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

**Expansion of trade and deregulation** offer greater opportunities to introduce fake products into official channels.

**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 political will:** in some countries counterfeiters are not disturbed by authorities if their export capacity takes priority over the public health value of medical products.

**Lack of awareness among health professionals and consumers** hinders detection and reporting, even when patients experience treatment failure.

## WHAT PRIORITY ACTION SHOULD COUNTRIES TAKE?

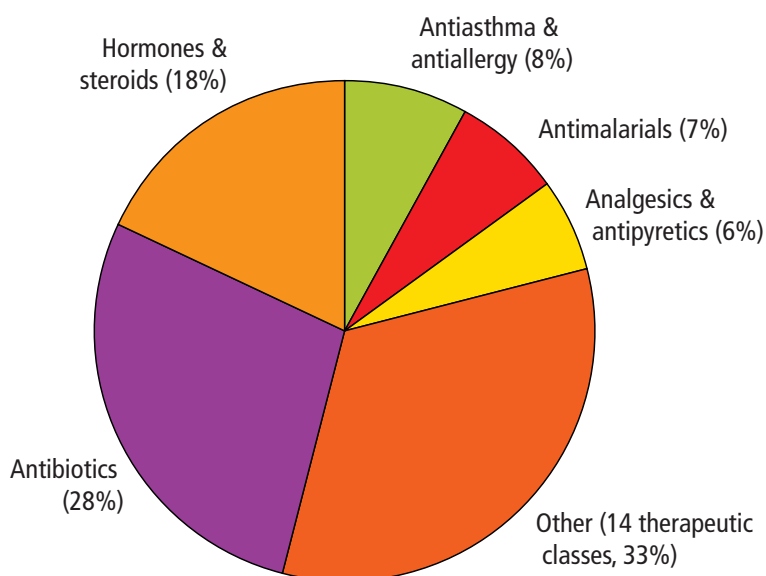
Strengthen legislation ensuring that counterfeiting medical products is a crime and that punishment is commensurate to the consequences that it has on personal health and on the credibility of national health care delivery systems.

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.

### Reports of counterfeit drugs by therapeutic class received by WHO 1999-2002



- 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, while other developing countries have less than 10%; overall, a reasonable estimate is between 10% and 30%

- 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 sites that conceal their physical address are counterfeit in over 50% of cases.

The estimated ranges do not aim at providing an exact figure but rather an indication of the different possible levels of prevalence around 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

Fake medical products are increasingly present even in better controlled markets, as shown in the following examples:

- April 2007: the United States Food and Drug Administration (FDA) 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.

- 2006: In the United Kingdom, officials seized 5000 packets of counterfeit flu medication oseltamivir.

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.

### The size of the problem

Currently, the sources of information available include reports from non-governmental organizations, pharmaceutical companies, national drug 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.

Although precise and detailed data on counterfeit medicines is difficult to obtain, IMPACT stakeholders estimate proportions ranging from around 1% of sales in developed countries to over 10% in developing countries, depending on the geographical area. That range takes into consideration both regional disparities in the presence of counterfeits, and specific global market value shares. 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.

- 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. less than 1% of market value

- 2006: In the United Kingdom a Recall Alert was issued on counterfeit atorvastatin, a cardiovascular medicine.
- 2004: In France, counterfeit contact lenses were detected by the regulatory authorities after receiving complaints from patients.

### Internet sales

In industrialized countries and to some extent in poorer countries, Internet-based sales of pharmaceuticals are a major source of counterfeit medicines, threatening those who seek cheaper, stigmatized or unauthorized treatments. Some Internet pharmacies are completely 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.

### Key challenges to halting counterfeit medicines

Counterfeiting medicines 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 and police, customs, the judiciary, manufacturers, wholesalers, retailers and health professionals.

Some policy-makers have argued that drug regulation represents an unnecessary barrier to trade and should be reduced to a minimum. Pharmaceut-



icals, 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 drugs does not require large infrastructures or facilities. The majority of the counterfeiters apprehended so far carried out their activities in ordinary homes, 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.

In many countries people have inadequate access to health services, 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 popula-

tions 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 drugs, 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 drug 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 of WHO Member States and a num-

ber of other stakeholders. These include: Interpol, Organisation for Economic Co-operation 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 police, customs officials and the judiciary. IMPACT stakeholders are looking at existing laws in countries and aim, **by the end of 2007**, to present effective models countries can replicate and adapt to meet their own

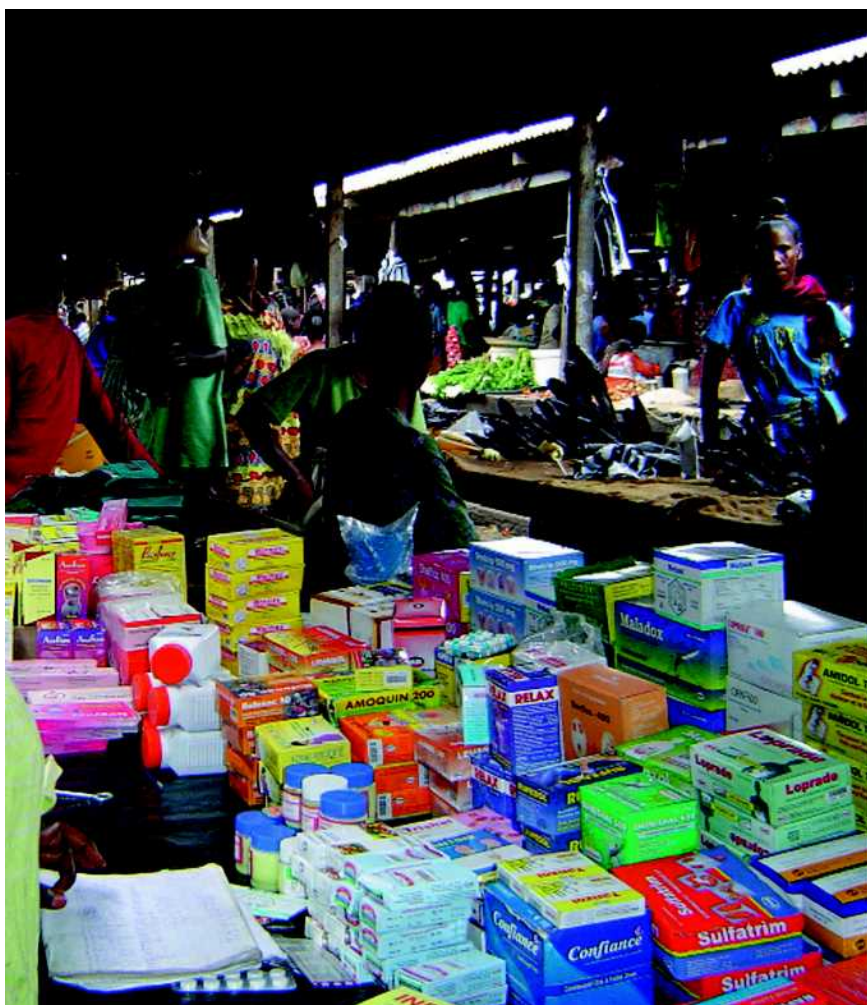
needs. These models will cover all the administrative, civil and penal aspects of legislation aimed at combating counterfeit medical products.

### **Regulatory implementation**

IMPACT stakeholders are working at ways to help national authorities to take action and implement legislative 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 and other expressions of the civil society 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 the World Customs Organization, INTERPOL, and informal networks of enforcement officers, the Permanent Forum on International Pharmaceutical Crime, IMPACT offers an important opportunity for 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. The enforcement working group is working also at developing training materials for enforcement officers of countries that need to improve their technical skills in the detection of suspected counterfeits



Where do these medicines come from?



Can you tell which one is fake?

and collection of appropriate evidence for prosecution.

### Technology

By using the broad partnership ranging from health agencies to pharmaceutical manufacturers and distributors, IMPACT will help to assess 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 aims at demonstrating the benefit of chosen technological approaches to the patient.

**There is no such thing as a “world-wide” applicable technology**, and therefore different approaches are needed when considering counterfeit medicines in the developing world versus the developed world. For developing countries the priority is to strengthen their capacities to tackle the informal trade of medicines such as street markets, smuggling, theft and other unregulated or illegal activities. Both developing and developed countries should implement **technologies appropriate to their situation** and seek 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 its cost, privacy concerns, logistics throughout the distribution system, etc.) and IMPACT found consensus on the fact that full implementation of **RFID can only be envisaged in a distant future**; as a consequence, alternatives need to be sought for individual pack coding today.

Technologies are particularly important for product authentication. The many different models for authentication include those aligned to end user verification (e.g. patient, doctor) and those focusing on the point of dispensing, with the pharmacist playing a vital role. 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 is developing the most coordinated and effective mechanisms required to both respond and alert key audiences, stakeholders and the general public about counterfeits in communities and across countries. This entails improving countries’ capacity to estimate the prevalence of counterfeit medical products and strengthening international information networks to exchange information and issue

alerts from country to country and region to region. 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.

# 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

## 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

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



Support, additional information: [www.who.int/impact](http://www.who.int/impact)