



## Increasing efficiency in the fight against fake medicines

### 1 – Fighting counterfeit medicines : the costs

The fraudulent activity in counterfeiting medicines is continually growing worldwide and has now reached unprecedented levels. Hundreds of thousands of children, women and men are victims of the greed of organized criminal networks.

Counterfeit medicines against malaria and TB alone are responsible for 700,000 deaths per year (2009 figure - International Policy Network). In Africa, rates of counterfeit drugs vary between 30% and 70% depending on the country; 30% in Latin America and 1% in developed countries (World Health Organization). 50% of medicines sold on the internet are fake or at least non-compliant (WHO) and 95% of existing sites sell fake drugs.

It focus on key therapeutic areas: malaria treatment, antibiotics, diabetes, Hepatitis, TB, AIDS, vaccines, oncologic medicine and veterinary products. In France it's mainly erectile dysfunction, dieting and anabolic.

Regarding the content of counterfeit medicines: in 1/3 of cases, there is no active ingredient; in 20% the amount of active ingredient is incorrect and for 8,5% content has a high level of impurities and contaminant.

Of one million annual malaria deaths, 200,000 deaths could have been avoided if patients were treated with real drugs (WHO).

According to the United Nations Office on Drugs and Crime (UNODC), forensic testing has demonstrated the extent of the problem in South East Asia. The anti-malarial studies indicate that 30 to 90% of the drugs tested in Southeast Asia are fraudulent. Studies of on other anti-microbial drugs indicate similar rates of failure.

It is not uncommon for counterfeit ingredients to be sent from China to Southeast Asia for production and packaging. These extended transnational networks are inherently flexible: if any supplier or assembler is arrested, other partners will be found. As law enforcement and regulatory pressure has increased within China, key major aspects of production are moved to other countries, such as the Democratic People's Republic of Korea, Myanmar and Viet Nam.<sup>18</sup>

Those selling fraudulent essential medicines seem to target low-value markets in Southeast Asia and Africa, where consumers spend less than USD 100 a year on pharmaceuticals. For example, looking at

selected Southeast Asian countries, pharmaceutical expenditures per capita varies widely, between USD 14 and USD 58 in 2010.

### **1.1 - An extremely lucrative activity**

If consumers in Southeast Asia bought around USD 8 billion in pharmaceutical products in 2010 and 47% of them were fraudulent, this represents around USD 4 billion in fraudulent expenditures that year. If, in keeping with the World Customs Organization (WCO) seizures in 2010, 60% of these drugs originated in China, then the total flow to Southeast Asia and Africa would be just under USD 5 billion.

It is extremely easy and cost-effective to produce a fake drug which might have the appearance of a genuine one. It explains in part why medicines infringement has become the favorite counterfeiting activity for mafia and criminal networks

### **1.2 - Risks of Punishment are too low**

Legislation in most countries does not take into account the threat for public health. It does not establish sufficiently severe punishments to deter drug counterfeiters. In many countries, the legislative apparatus deals with the falsification of medicines in the same way as for any other form of counterfeiting, i.e. exclusively as an industrial property violation. Thus, medicines-faking offenders often incur the same penalties as those that would apply to a counterfeiter of branded T-shirts, DVDs or handbags.

Some countries do have sufficient and appropriate legislation (about 20% according to the WHO), but do not apply it properly.

30% of countries have little or no regulation to effectively combat counterfeit drugs (WHO).

Counterfeiting genuine medicines is seen by criminals as an easy way to making big bucks with lower penalties than those applied to producing and trafficking narcotic drugs.

### **1.3 - The lack of transnational jurisdiction and consensus**

Nearly the entire fight against trafficking in fake medicines relies on national legislation for legal measures and on state authorities for law enforcement.

The fact that not all countries recognize medicine counterfeiting as a specific crime, in the same way as terrorism or trafficking in false currency for example, undermines the effectiveness of enforcement actions in the field.

This legal and organizational vacuum often leads to the impunity of drug counterfeiters whose industrialized and highly organized trafficking plays on international discrepancies. The raw materials used in the production of a fake drug come from one country; the drug is manufactured in a second one; it passes through a third one and the final product is marketed in a fourth or a fifth, etc.

Until now, only one international convention has been adopted (the Medicrime Convention prepared by the Council of Europe in 2010) and only ratified by 9 States in the world!

### **1.4 - Lack of means and training of players in the field**

Fake medicines trafficking networks use their enormous financial resources to equip themselves with sophisticated technical means for production and logistics and to develop elaborate escape strategies. Today, product imitations have reached such a high level of perfection that it has become very difficult, sometimes impossible, to visually distinguish a genuine drug from a fake.

Faced with these devices and the complexity of counterfeit products, stakeholders who are able to fight against this traffic (doctors, pharmacists, customs officers, police) rarely have equivalent resources.

Moreover, they must have high levels of expertise in the required technical skills and methodological know-how to be effective in the daily struggle.

There is a lack of competent international training bodies and of physical or virtual spaces for players in the field to share experience and best practices. This significantly impedes the efficacy of their preventive and enforcement actions.

## **2 – IRACM : Our organization**

### **2.1 – Why IRACM was created**

IRACM is a French association governed by the law of 1901.

IRACM's mission is to mobilize the stakeholders, make the national authorities aware of the need to attack this scourge and encourage the general public to take part in the fight. The aim is to group together all the parties concerned. We are already training the people involved at grass roots to combat fake drug trafficking. For IRACM, the priority is also to centralize knowledge, good practices and expertise, be a representative and consultative body to help national and international political and judicial powers.

The creation by Sanofi in 2010 of the International Institute of Research Against Counterfeit Medicines (IRACM) reflected a heightened awareness and responded to a need to act. Today, the counterfeit medicine problem is spreading fast all over the world, as transnational organized crime networks are increasingly turning to this type of crime, which can be 20 to 50 times more lucrative than narcotics.

All too often governments do nothing to stem this growing threat. They act only after the events and then only to a limited extent.

Yet it is a serious danger to international public health, a terrible threat to rule of law and a grave peril for pharmaceutical laboratories.

### **2.2 - IRACM in the early days**

Initially, IRACM pioneered in training international law enforcement authorities, those working directly to fight counterfeiting. We intend to promote in-depth knowledge of the problem and increase the awareness of political leaders and decision makers, and of public opinion. In 2014, the Institute, together with the UNODC, initiated the drafting of a model law.

Since its inception, IRACM has endeavoured to become a centre of excellence totally dedicated to the fight against counterfeit medicines. The past five years have seen an emphasis on training and informing healthcare practitioners, police officers and health regulators. So far several thousand people have been made aware of the dangers of counterfeit medicines.

The International Institute of Research Against Counterfeit Medicines (IRACM) is at present the only international independent body exclusively dedicated to combating counterfeit and fake medicines, primarily through information, prevention and training.

The Institute has become an internationally renowned specialist in its field of expertise.

### 3 - Our priorities

IRACM is doing its best to develop a global strategy at the political, legal and operational levels and in terms of prevention:

1. *Raise awareness of, and involve and mobilize governments*
2. *Assist States improve their national legislation and international judicial cooperation*
3. *Develop, intensify and extend the training courses*
4. *Support a greater number of operational actions in real time*
5. *Develop prevention campaigns aimed at patients and increase communication towards the general public*
6. *Deepen knowledge of the phenomenon of fake medicines.*

### 4 – How do we operate

Many people simply stress the need for intensive police and customs officer training in counterfeit medicine prevention and an increase in their numbers and resources. However, this is not enough. The work of police and customs officers will serve no purpose if their government is not willing to tackle the problem with a viable strategy. States need tough legislation and relevant sentencing. States need the resources to create proper international legal support. States need judges, prosecutors and investigators trained and motivated to effectively provide this international legal support.

The International Institute of Research Against Counterfeit Medicines (IRACM) is developing a number of international actions to raise awareness, mobilize, inform and raise the alarm.

#### **4.1 - Political commitment: Convince governments to acquire the means to combat pharmaceutical crime successfully**

*Governments will only agree and take action if they are convinced of the severity of the problem and urgent nature of the fight required.*

A comprehensive political action becomes possible if they recognize the need to prioritize the fight against fake medicines, to define a national strategy, and to develop a proactive attitude.

Our challenge therefore is to assist States in defining strategies and encourage them to form regional synergies. Meetings between senior government representatives lead to adopting effective strategies and a proactive attitude.

The Institute has begun a strategy to make governments aware of the falsification of medicines worldwide. Of course, the poorer countries are the worst affected, but they are by no means the only ones. Counterfeiters also target developed countries through the sale of medicines and pharmaceuticals on Internet.

IRACM has defined some main priorities : Western and Central African States, South East Asian States, Latin American States

#### **4.2 - Modernization and effective implementation of national laws and international conventions**

Governments have to enact modern comprehensive and appropriate legislation, not only focused on intellectual property rights but also taking into account specific dangers generated for public health by fake medicines. They have to adopt dissuasive scales of punishments too. An appropriate scales of punishment is required in the criminal code with a maximum time at least to over four years' imprisonment when punishing trafficking in counterfeit medicines

IRACM assist States to set up international conventions and effective national laws. The ratification and use of conventions such as Medicrime and the Palermo Convention are essential, as is the drafting of more comprehensive model legislations that are tailored precisely to counterfeit medicines. A process is already underway with the UNODC, due to be finalized in September 2017.

The model law under development with the Syracuse International Institute of Higher Studies in Criminal Sciences (ISISC) covers all the fields in which the States need to pass laws for a comprehensive, modern and effective national legislation to tackle the counterfeiting of medicines. One specific version is prepared with representatives of 7 African States and will be ready in September 2017

#### **4.3 - Training investigators, custom officers, prosecutors and judges**

Action has to be taken to truly change day-to-day legal practices to motivate and train legal operators, and ensure they are operational and effectively apply the law.

Main targets: Train the agents at the front line, particularly police and customs officers in the sensitive zones effectively and practically: over 2,000 people have been trained in counterfeit medicines worldwide in more than four years. IRACM's expertise is requested and appreciated in numerous countries.

Ongoing actions: IRACM is now training grassroots players to deal with counterfeit medicines in priority regions such as Africa with Togo and Niger, Latin America with Mexico, Asia with Singapore and Mekong, and Europe.

Since December 2014, the Institute has extended its training courses to the general public by putting a fun and comprehensive e-learning course on counterfeit medicines online with free access for all. It is available in three versions: French, English and Spanish. Seven modules have been written

explaining how medicines are manufactured, marketing, the fight against counterfeiting, the applicable legislation, and finally counterfeiting on Internet and how to authenticate a box of medicine. This e-learning course has been widely distributed to all countries via a web marketing campaign and has been taken up by numerous sites that are sensitive to health issues.

#### **4.4 - Operational support for interception of containers**

Since 2012, IRACM has been lending its support to operations aimed at intercepting containers led by the World Customs Organization (WCO) in Africa. The four successful operations led to the interception of 502 suspicious containers and nearly 869 million illegal and counterfeit pharmaceutical products. The joint operations of IRACM and the WCO have received widespread and active media coverage.

Other international organizations, like Interpol, are partners and essential players in spreading greater awareness of counterfeit medicines through international conferences.

#### **4.5 - Regional cooperation**

Governments have to secure the effectiveness of mutual legal assistance between the law enforcement and judicial authorities of the countries along the route used by the traffickers of counterfeit medicines. Regional agreements have to be adopted in line with the Palermo Convention to facilitate the judicial cooperation, including to locate the criminal assets and to freeze them.

Regional cooperation has also to be developed in the field of prevention. In November 2013, IRACM mobilized four First Ladies of Africa (Niger, Mali, Burkina Faso, Equatorial Guinea) in Niamey, Niger, who committed to combatting the proliferation of counterfeit and sub-standard medicines and signed the Niamey Declaration. That was the first step in a series of operations to be implemented in African countries, including the creation of an information kit for school children.

#### **4.6 - Develop communication on the fight against counterfeiting and its ill effects**

Communication is essential to raise awareness around the world. Our website contains a wealth of information and is constantly updated. In 2017, the role of IRACM, the tasks and work we have already done are more known. Our image and reputation have been built up through these events and are now known worldwide. The IRACM website has an international press review on counterfeit medicines, pages focusing on specific topics, a presentation of the actions we have taken, legislation, a glossary, the background and also a map of all the seizures recorded by the Institute.

The emphasis is on press relations. We have activated a network of journalists and built up a panel of targeted journalists who are deeply concerned about the matter. IRACM intends to increase its visibility in the national and international media.

In 2014, IRACM developed its social media by creating a TV channel on YouTube and pages on social networks like Twitter, Facebook and Google+. The general public is then directly informed.

In 2016, IRACM raised awareness to the general public through information campaigns with advisory leaflets for patients in doctors' waiting rooms in France, and by a web campaign in Latin America.

#### **4.7 - Positioning the IRACM as an international leading figure**

IRACM has become an internationally renowned center of excellence targeting an ever-increasing audience of political leaders, international organizations, pharmaceutical laboratories, law enforcement institutions, patients, public opinion and the media.

In September 2013, IRACM published an authoritative study report on organized crime and counterfeit medicines. The report was presented to the press on 23 September 2013, and was very well covered by the media. It is still one of the most often-consulted documents on the IRACM website.

The Institute highlights its partnerships and its in-depth knowledge of the subject of counterfeit medicines, has created a reference list of global information about the issue, has built up a virtual and physical library, and continues to produce studies on counterfeiting.