Overview of global counterfeit medicines

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I. Introduction

Risks linked to intellectual property rights (IPR) and Health and safety issues in the customs context largely refer to goods, such as fake or counterfeit pharmaceuticals and other dangerous counterfeit and pirated goods.

About pharmaceutical products, Interpol and the World Customs Organization (WCO) prove, year after year, the criminal reality of illicit trafficking on health products and sustainable development of their market.

In this context, Interpol and WCO promote concrete law enforcement actions in the field with the ultimate aim of protecting the public from sub-standard and dangerous goods. On-the-ground operations are run on a national and regional level in order to disrupt transnational criminal networks involved in pharmaceutical crime. Directed at both physical outlets and Internet suppliers, these are multi-agency efforts supported by key scientific partners.

Their flagship operations from 2010 to 2013 with:

- Giboia (5 African countries),
- Biyela (23 African countries),
• Cobra (7 African countries),
• Pangea (99 countries targeting Internet),
• Mamba (5 African countries)
• Storm (Southeast Asia),

continue to go from strength to strength. Successive raids on licit and illicit markets have shown improved results in terms of seizures, arrests, convictions and the closure of illicit websites.

Results from the last operations clarify the reality of illicit markets:

Operation Giboa (1-3 October 2013)
Participating countries: five in total (Angola, Malawi, Swaziland, Tanzania and Zambia)

Results:
• Almost 100 tons of illicit medicines were seized, including illicit and counterfeit versions of antibiotics, birth control, anti-malarial and analgesic medicines;
• The seized illicit and counterfeit medicines, both branded and generic, are estimated to be worth approximately USD 3.5 million;
• Diverted and expired medical products were also identified;
• 181 suspects were arrested or placed under investigation;
• Nine outlets unauthorized to sale medicines were closed across the five participating countries;
• Two illegal clinics employing unqualified staff were closed in Malawi.

Operation Pangea VI (18-28 June 2013)
Participating countries: 99 in total

Results:
• 10.1 million illicit and counterfeit pills confiscated;
• Estimated value: USD 36 million;
• More than 13,700 websites shut down;
• Some 534,000 packages inspected by regulators and customs authorities, of which around 41,000 were confiscated;
• Some 213 individuals are currently under investigation or under arrest for a range of offences, including illegal Internet activity, illegal sale of medicines and supplying unlicensed medicines.

Operation BIYELA (April 2013)

Results:
• More than one billion articles;
• 550 million doses of illicit, potentially dangerous including: antibiotics, painkillers, anti-inflammatory medicines, medicines for high blood pressure and diabetes and food supplements.
• Estimated value: USD 275 million.

Cobra 2011 (26 September – 2 October 2011)
Participating countries: (7 in total) Burkina Faso, Cameroon, Ghana, Guinea, Nigeria, Senegal and Togo

Results:
• Seizure of 170 tons, and almost 200 packages and 5,500 boxes of medicines;
• More than 300 different medical products seized;
• Outlets unauthorized to sell pharmaceutical products closed down;
• More than 100 individuals arrested, including unlicensed street sellers, unlicensed dealers and suppliers.

Operation Mamba III (July-August 2010)
Participating countries: Burundi, Kenya, Rwanda, Tanzania (including Zanzibar) and Uganda

Results:
• More than 375 premises targeted;
• Nearly 200,000 pills seized;
• At least 120 police cases opened;
• 78 cases were sent to court;
• At least 34 convictions pronounced.

Operation Storm II (January 2010)
Participating countries: Cambodia, China, Indonesia, Laos, Myanmar, Singapore, Thailand and Vietnam

Results:
• 20 million pills seized, including antibiotics, anti-malarial and birth control medicines, anti-tetanus sera, Aspirin and erectile dysfunction medicines. (Of these 20 million pills, more than 12 million were counterfeit, while nearly 8 million pills were expired, not registered or diverted medical products.)
• More than 100 pharmacies and illicit medicine outlets closed;
• At least 33 suspects arrested.
These results reveal the extent of the traffic of illicit medicines in the southern hemisphere, and the danger this poses to the health of people across the African and Asian continents.

But, what about the northern hemisphere?

Saying that medicine counterfeits account for 10% or 15% of the global pharmaceutical market is irrelevant. Civil cases relating to IPR cannot be compared with criminal cases that directly endanger patients’ lives. Likewise, the figures declared by the pharmaceutical industry for financial prejudice due to endemic counterfeit trafficking ($35 billion in 2006, $45 billion in 2010 and $75 billion in 2012) are not realistic.

On 30 April 2009, during its 72nd World Health Assembly, the World Health Organization (WHO) presented the findings of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) in order to decide on new measures against the explosion in the international sale of counterfeit medicines, which accounted for a third of all medicines in Africa and a quarter in developing countries in general. While praiseworthy, these measures appear to be difficult to implement knowing the slowness in the application of these directives in the 160 WHO Member States. The most pessimistic experts say that while the WHO is struggling to push through an international treaty to define the word “counterfeiting”, malfunction and failures in emerging and developing countries will prevent it from treating the real causes of counterfeiting.

International experts estimate that 75% of global counterfeits come from India and China, and half go through Dubai in order to conceal their origin. The governments of the worst affected countries often promise “control” measures, adopt new laws and propose harsher sanctions. However, counterfeiting continues to flourish.

On the other hand, according to the pharmaceutical industry, the level of counterfeiting in developed countries is below 3%. Some people explain this by the existence of strong regulators such as the US Food and Medicine Administration (FDA), despite the millions of medicine shipments that slip through US Customs every year and end up being sold by some 9000 wholesalers and European agencies. However, FDA says that it is unable to control such large volumes. So what is stopping even more of these counterfeits from getting through to such a lucrative market? Brand medicine manufacturers explain this in part by the basic principles underlying rich country economies, such as strong brand protection, which gives consumers a guarantee of the origin of products. Even if their detractors claim that brands are only relevant for expensive and patented medicines, manufacturers consider that it is the other way around. The majority of medicines consumed in both rich and poor countries are “generics”, in other words medicines whose patents have expired, which should create a dynamic brand generic market, where competition focuses on only on price, but also on quality. Pro-brand manufacturers also argue that poor brand protection in developing countries means that patients can rarely be sure whether the generics they buy are genuine medicines (non-patented medicines are some of the most frequently counterfeited medicines).

Civil liability law in rich countries ensures that wronged consumers obtain compensation from the courts, thereby deterring counterfeiting and those who sell counterfeit products.

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1 WHO Secretariat Report A62/14 of 30 April 2009
2 Dakar, 16 Sept 2009 – “The defendants M.T.N and K.T. charges with illegally selling pharmaceutical products, were
This understandable reasoning, propounded by right holders, can only work in functional, independent and corruption-free legal systems. Unfortunately, the courts and police forces of the majority of developing countries do not fulfil this ideal and let criminals get away with in exchange for bribes, making any new laws largely ineffective. The verdict issued in Dakar in September 2009 is a prime example of this.²

Often, additional laws increase the levels of bureaucracy, thus increasing the opportunities for corruption. In the case of medicines, when they go through customs, they have to go through a number of customs regulations and tariffs, which inevitably leads to “informal” payments in order to expedite the procedure. If the market is small, as in many African countries, many authentic medicine suppliers tend to consider the obstacles too expensive and are quick to stop supplying such countries, leaving the door open for counterfeiters, who do not comply with the regulations and therefore make higher profits. In addition, many developing countries impose high taxes as well as complex regulations on imported medical products, thus increasing the average final price by 68.6% according to the WHO. Customs taxes or duties alone represent around 20% of the cost of medicines: from a 14% tax on sales in South Africa to 30% in Brazil and more than 50% on all imports in India (and at least 19% for local medicines). Authentic medicines are therefore more expensive, making it easy for counterfeiters to push them out of the market.

Although strengthening the rule of law is essential in the fight against pharmaceutical counterfeiting, as well as for economic development in general, the procedure is long and hard. In the short term, technology can help the manufacturers of authentic products to protect their brands. In Ghana, a new service called MPedigree allows consumers to send serial numbers (included on the packaging of the medicines that they have bought) by text message to receive a message telling them whether the product is authentic or not. Many similar programmes are currently being developed. But does this really deal with the fundamental problem? Technology can only support a strong enforcement policy based not only on the authority of intellectual property law - often absent in these countries - but also and above all on the sovereign criminal-law legislations of each State.

For all intents and purposes, criminal proceedings are the way forward. One only needs to consider a few chronological examples to understand the truth in this “anthological” checklist in appendix 2.

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² Dakar, 16 Sept 2009 – “The defendants M.T.N and K.T. charged with illegally selling pharmaceutical products, were sentenced to 4 months imprisonment on Thursday by the regional court of Dakar. According to the civil party’s lawyer, who was defending the Order of Pharmacists of Senegal, the defendants are all guilty as charged. He specified that M.T.N and his acolyte K.T. has tried to bring boxes of medicines sent from Touba into Dakar. The civil party lawyer also indicated that the medicines, with an estimated value of 4 million FCFA, were counterfeits from Nigeria, and other expired medicines. He claimed that the defendants had tried to take their goods into Dakar through the Sangalkam via Rufisque. Referred to the Office of the Public Prosecutor, they admitted to their crimes and declared that the medicines were intended for “Keur Seigne Bi”. In the lawyers opinion, the Order of Pharmacists of Senegal filed civil proceedings to bring the defendants to justice. He requested that the court hand down severe sentences to the defendants, who had defied the authorities by selling illegal medicines on the streets of Senegal and elsewhere. The civil party lawyer requested 6 million francs in damages. The lawyer for the defence highlighted that the charges against his clients were constant and has been confirmed. He requested that the court be lenient, since according to him, the sale of medicines at “Keur Serigne Bi” and on the streets has been happening for a long time and these individuals has been carrying out this activity over a number of years to be able to feed their families. The defence lawyer pleaded for a lenient enforcement of criminal law stating that the Senegalese that sell these products are only trying to survive and earn money to help their families that have remained in the villages. The district court, after deliberating, condemned M.T.N. and K.N. to 4 months’ imprisonment each and to pay a joint fine of 500,000 FCFA to the civil party.” – APS.
It is also interesting to list a few of the cases found during the last months of 2013 in the United States:

- Dr. David Fishman of Ohio Sentenced to Probation in Misbranded Cancer Medicine Case: November 19, 2013
- Florida Man Sent to Prison for 2 Years for Selling Unapproved Imported Cancer Medication: October 18, 2013
- 7 Ohio Oncologists Charged with Illegally Importing Non-FDA approved Cancer Medication: August 13, 2013
- Kentucky OB/GYN Sentenced to Probation For Purchasing Counterfeit IUDs: August 12, 2013
- Clandestine Pharmaceutical Distributor in Virginia That Posed As Canadian Company Shuttered, 11 Indicted: August 7, 2013
- Utah Businessman Sentenced to Year in Prison For Importation of Non-FDA Approved Medicines: July 31, 2013
- British Owner of Fake Cancer Medicine Distributor Sentenced in Federal Court: July 11, 2013

In order to understand this alarming report, we will begin by describing the different forms and economic impacts of counterfeit medicines that exist in order to place the situation of pharmaceutical counterfeiting in an international context.

II. Background and definition

The diversity of definitions in the field of counterfeit medicinal products creates real difficulties for focusing the trends of pharmaceutical crime and its markets development. These are called “Counterfeit medicines” for some experts, “fake or falsified medicines” for others. For the purpose of the current report, the generic term “Counterfeit medicines” will be used.

For the WHO, counterfeit medicines can be grouped into different categories as under:

- Products without active ingredients;
- Products with inadequate quantities of active ingredients;
- Products with incorrect active ingredients; and
- Products with correct quantities of active ingredients but with the wrong name of manufacturer and/or country of manufacture indicated on the label.

For its part, in 2011 UNODC adopted a resolution in the Crime (Resolution 20/6) on the issue of fraudulent medicines, giving a definition of “fraudulent” or “falsified” medicines as: “falsified medicines, usually referred to as falsified medicines, include purported medicines whose contents are inert, are less than, more than or different from what is indicated, or have expired”. This definition excludes both Intellectual Property Right (IPR) and sub-standard medicine issues.

Recognising these definition difficulties, participants at the first OECD TF-CIT working-group meeting on counterfeit medicines collectively decided to combine both the WHO and UNODC definition approaches:

Falsified/fake medicines with intent to deceive as a result to provide a product:
- without active ingredients,
- with inadequate quantities of active ingredients,

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• with incorrect active ingredients, and
• with correct quantities of active ingredients but with the wrong name of manufacturer and/or country of manufacturer indicated on the label, produced, distributed and sold in breach of national and international regulations.

III. Key reasons of counterfeit medicines

**Easy money** is the main driver for counterfeiters. Manufacturing costs are very low if quality and safety standards are "by-passed".

**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 princeps (originator medicine) and generic⁴, 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.

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⁴ Generic: usually legal only after the patent of princeps has expired, or if no patent was issued for the original substance. Generic medicines are usually less expensive than proprietary medications.
IV. Economic impact

Economic loss as a result of counterfeit medicines is enormous and appears to be increasing annually (Appendix 1). As mentioned in our introduction, about $32 billion were lost to counterfeit medicines business in 2004 (WHO, 2006). This increased to $40 billion US in 2006 and was projected to reach $75 billion in 2010 (WHO, 2006; Bate and Boateng, 2007). In 2013, it is difficult to confirm this prediction. However, such as the 2012 estimation check-listed per country within Appendix 1, financial ratios between illegal and legal medicines are very worrying. Many pharmaceutical companies are deprived of their rightful profits due to the unjust competition from this brutal crime and have even resulted in the collapse of some of the companies (Akunyili, 2005b).

Financial ratios (%) between legal and illegal pharmaceutical market

![Financial ratios between legal and illegal pharmaceutical market](image)

African Continent

About African continent, reports on counterfeit medicines indicate a wide variety of detrimental effects. In addition to those in public health, these include lost revenues to firms that might otherwise be used to develop newer and better products, lost taxes to governments responsible for public health, additional costs firms and governments incur to protect supply chains from counterfeit products, resulting disincentives to foreign investment, and consequent loss of jobs and economic opportunities.

Unfortunately, the exact extent of this problem, and therefore how best to combat it, is unknown. As a first step to address it, researchers at the Anti-Counterfeiting and Product Protection Program (A- CAPPP) of Michigan State University reviewed 30 open-source publications on it, including academic, governmental, private organization, and media reports. Most of these sources focus on revenue shortfalls to pharmaceutical manufacturers resulting from counterfeit
products, perhaps because of the relative ease of measuring revenue and tax streams. Nevertheless, they also offer insights on the broader health, economic, and social problems resulting from counterfeit pharmaceuticals.

Perhaps the greatest toll that counterfeit pharmaceuticals take is on public health. Malaria is estimated to cost African nations at least $12 billion annually in lost economic output. Tuberculosis is another public-health scourge in Africa; the economic cost of tuberculosis-related deaths, including those resulting from HIV co-infection, in sub-Saharan Africa is estimated to be about $50 billion annually. These losses are compounded by counterfeit pharmaceuticals. Of the one million malaria deaths that occur worldwide each year, 200,000 are reportedly the result of counterfeit anti-malarial medicines. The WHO also indicates that 700,000 Africans die annually from consuming fake anti-malarial or tuberculosis medicines, most of which originate from China and India. Counterfeit pharmaceuticals can also impair health by causing their users to develop a tolerance for the active curative medicine in them and making an ultimate cure even more difficult to effect.

Sales of counterfeit medicines take away from the sales of legitimate medicines. A 2009 United Nations report found sales of 45 million counterfeit anti-malarial medicines resulted in revenues for their providers of $438 million, more than the GDP of Guinea- Bissau. Another report contended counterfeit medicines sold in Kenya represent up to 40 percent of medicines sold, equaling approximately $130 million annually.

Counterfeit goods, including pharmaceuticals, have resulted in hundreds of millions of dollars in lost tax revenue throughout the African continent. The East African Community (Burundi, Kenya, Rwanda, Uganda, and Tanzania) reports more than $500 million in unpaid taxes as a result of counterfeit goods. Tanzania in particular reports losing between $370-617 million per year due to tax evasion related to counterfeit goods.

Counterfeits reduce economic incentives to develop new products and decrease brand value, brand reputation, and competitive advantage. There is limited information on how counterfeit pharmaceuticals affect these problems in Africa, but that on intellectual property more generally may help illustrate their effects. Nigeria is reportedly the largest market in Africa for goods that infringe intellectual property rights. By some estimates, the Nigerian pharmaceutical industry operates at less than two-thirds of capacity.

Economic analyses by the Organization for Economic Co-operation and Development (OECD) indicate that foreign direct investment from Germany, Japan and the US is relatively higher in economies with lower rates of counterfeiting and that multinationals are less likely to invest in countries where they are likely to have their products copied. Rights holders investing in Kenya reportedly lose an estimated $390 million annually to counterfeiting and piracy. Counterfeit pharmaceuticals in the region, in other words, is one small part of a larger counterfeiting and product piracy problem that leads to economic and job losses that in turn can cause greater demand for cheaper but ineffective counterfeit goods and exacerbate the public-health problems associated with these.

The costs to combat counterfeiting include those for public education, health care, supply-chain security, enforcement, prosecution, prison housing, and technology expenses. An A-CAPPP report provides one example of such costs, noting that if 140 million Nigerian citizens were to consume ten pharmaceutical packages per year.

Unfortunately, the reliability of the estimates on effects of counterfeit medicines is unclear. Estimates for many dimensions of the problem do not exist. Those that do are often imprecise on
their sources or methods. Acquiring reliable estimates of the economic effects of pharmaceutical counterfeiting in Africa is difficult for several reasons.

First, the trade of counterfeit goods is illicit, clandestine, and complex, which makes it difficult to identify and link to outcomes. Second, the pharmaceutical industry has competing interests in the sharing of data—it wants to encourage enforcement but not frighten consumers. Finally, there is little support for data collection and research. Yet policies and responses not supported by rigorous data and analysis can result in costly strategies that are ineffective. Assessing the true nature, extent, and cost of the counterfeit problem in Africa will improve our understanding of the problem, inform priorities and resource allocation for addressing it, facilitate interventions and solutions, bolster the evaluation of anti-counterfeit strategies, and, ultimately, result in the development and implementation of cost-effective promising practices.

**European continent**

We know from past experience that in times of crisis, health outcomes and the risk of health-related financial hardship may be affected by changes in the resources available for health systems (financial and human resources, medicines and medical devices, running costs and infrastructure), by changes in living conditions, lifestyles and consumer behaviours, and by changes in social norms and values. Ideally the health system can and should do three things: protect those most in need, concentrate on areas in which it is effective and adds value, and behave as an intelligent economic actor in terms of investment, expenditure and employment.

*Is EU safe?*

The health impact of the rapid deterioration in public finances is already strongly felt. In view of the levels of public debt, it is more than likely that the fiscal “room to manoeuvre” will remain limited. The deterioration of public finances and a consequent shrinking of fiscal space could force governments to adopt drastic adjustment and austerity measures. Resources for health systems could be under severe pressure in the years ahead. Health authorities and related stakeholders will have to navigate through particularly difficult times in the foreseeable future, including focusing on what will happen after the crisis (for a start, debts will have to be paid).

The effects of the crisis on health and health systems vary significantly from country to country, depending on the structure of their economy, their dependency on exports and/or fluctuations in their domestic currency, as well as the policy actions developed by their government. There will certainly be no “one size fits all” or ready-made approach. In such a context, solutions will have to be customized to meet countries’ specific needs. Exchange of information and experience between countries and coordination of activities will certainly be needed, but supporting the preparation and implementation of country-specific programmes has to be the top priority.

Any product marketed within the European Union must hold a specific marketing authorization which can be obtained through three types of procedures: a centralized procedure whereby the authorization is issued by the European Medicines Agency (EMA) and is valid in all European Union countries; a decentralized procedure whereby the authorization is issued by the competent national authority (for example, ANSM in France) but which can be extended to other Member States according to the principle of mutual recognition; and a national procedure whereby the authorization is issued by the competent national authority and is only valid in that country.

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Having understood the process control of pharmaceutical products inside the European Union, two major problems are highlighted: Parallel importation and distribution for one part and Internet for second part.

Parallel importation and distribution within the European Union concerns products bought in a EU country for the sole purpose of selling them on in another EU country. This phenomenon can be explained by the price difference between countries for one same product. However, in the pharmaceutical industry, this practice is magnified by the price controls carried out by each State authority on medicines.

A distinction must however be made between “parallel distribution” and “parallel importation”. The “parallel distribution” of medicines refers to cases where a centralized Community marketing authorization is valid in all Member States and the authorized medicine is distributed by an importer that is independent of the manufacturer. In other cases we refer to parallel importation.

Having examined the general legal basis (EU Treaty) governing parallel distribution and importation in the European Union, we will provide an overview of the pharmaceutical regulatory framework as well as its implementation, especially in light of European Court of Justice case law (ECJ). The absence of barriers for parallel importations in the form of trademarks and patents will also be briefly touched upon. Lastly, we will consider the risks of counterfeiting resulting from the interpretation of EU texts that promote free trade within the European Union.

The parallel distribution and importation of medicines in the EU are a result of the combination of two articles in the EU Treaty. Article 28 EC forbids quantitative restrictions on imports between Member States and all measures with equivalent effects. However, article 30 EC provides for these restrictions on grounds of protecting the lives of individuals and where they do not constitute a means or arbitrary discrimination or a veiled trade restriction between Member States. Accordingly, specific regulatory provisions have been produced for the implementation of this principle of free trade in the pharmaceutical sector.

It is also important to remember that under directive 2001/83/EC of the Community code relating to medicinal products for human use, no medicine can be marketed in a European Union country without having previously obtained marketing authorization. This marketing authorization can be, subject to certain conditions, a centralized or decentralized Community authorization. Moreover, this regulatory framework is better understood when a distinction is made between parallel distribution and importations.

With regard to parallel distribution, the only authorized modifications to the product are the language in which the text on the label and the instructions is drafted, and on rare occasions, the size of the packaging. Proof of the imperative necessity for these changes must be provided before the product can be distributed in parallel in the destination Member State under the same conditions as the product distributed by the marketing authorization holder.

In general, different sizes relate to differences in medicine distribution in each country. Once a Community marketing authorization has been issued for the medicine, it can circulate freely within the European Community, without requiring a new authorization. The parallel distributor only needs to submit a notification to the European Community (i.e. the EMA) and the authorities of the Member States (where the medicine will be distributed).

Any objection by the competent authority must be notified within 30 days and must indicate its grounds for objection in detail. Parallel distributors must, as wholesale distributors, fulfil the
obligations that apply to them under articles 5 and 8 of Directive 92/25/EEC (integrated into the 2001 Community code relating to medicinal products for human use).

Both in parallel distribution and importation the implementation of the provisions of the EU Treaty relating to medicines permits almost total freedom of movement for products between European Union countries without the application of any specific customs control. The possibility of control on public health grounds is marginal in comparison with the implementation of the principle of free movement in article 28 EC.

Considering the serious health threat posed by a counterfeit medicine, doubt as to the origin of a product claiming to be an authorized medicine cannot be tolerated. Over the years, Community case law has only strengthened the primacy of the principle of free movement over public health concerns by giving an increasingly restrictive interpretation of article 30 EC.

While the enlargement of Europe requires particularly onerous efforts on behalf of new Member States to meet community standards, often requiring administrative reorganization, it is important to make sure that, in terms of counterfeiting, this "transition" period does not have the secondary effect of lessening the effectiveness of controls, especially at EU borders.

In the event of such an enlargement, European regulations on parallel importations could increase repackaging stages, thus facilitating the reuse of authentic packaging for illegal purposes. In addition, there currently exists a dispensation for the packaging of product batches imported to the EU, which could lead to packaging "errors", hampering traceability and surveillance.

The danger of parallel re-importation, mentioned in the Esambert report (report to the delegate minister for exterior trade on the fight against parallel re-importations of medicines- February 2003) seems to have been solved by the Cancun Agreements whereby packaging will display different marking in Southern destination countries; the European Commission thereby hopes to promote the local production of medicines, thereby providing an up-hill solution to the problem.

Moreover, the rationalization of production and distribution methods means that a product crosses the border various times before it is placed on the market. For example, a product that is manufactured France can be exported for packaging (7% of intra-group exports), and then re-imported for distribution worldwide. This method of distribution leads to a multiplication of exchanges and therefore of the risks of the illegal handling and distribution of substandard or counterfeit products.

According to the 2012 annual report of Taxud, approximately 40 million products believed to be infringing IPR were detained by EU customs. In total the products were attributed a value of €1 billion. Despite these figures being lower than those for 2011 the 2012 figures are worryingly high and shows that more needs to be done to prevent IPR suspect goods from entering the European Union. Suspect cigarettes account for the greatest portion of the fake goods seized. The second largest portion of seized goods consisted of miscellaneous goods such as lamps, bottles, batteries and washing powder. Other suspect goods seized were packing materials. However, proportionally to the seizures of 2012, the number of retained pharmaceuticals is low 712,220 Articles\(^6\) for an amount estimated at € 8,152,653 (provenance from China about 48%, India about 16% and Hong-Kong about 14%). This very modest figure could be explained for two reasons.

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\(^6\) The number of articles is counted as numbers of individual pieces unless otherwise specified.
The first reason is that the market for illicit medicines in Europe is not yet sufficiently interesting target financially to take the risk of developing a criminal distribution network. The second reason is the limitation of control further to the Nokia’s judgment prohibiting controls on goods in transit.

On the other hand, Internet becomes a matter of concern, demonstrating the interest of European citizens for cheaper pharmaceuticals, easier to buy and in particular without medical supervision. Operation Pangea VI Conducted by Interpol, Europol and WCO between 18 June and 25 June 2013\(^7\) shows that the threat in the European Union is real.

Globally, Operation Pangea VI resulted in 58 people being arrested worldwide and in 9,610 illegal online websites that were selling counterfeit and unlicensed medicines being closed down or suspended through domain name or payment facility removal.

Counterfeit pills worth £12 million have been seized in the UK during the global crackdown. Investigators seized three million doses of unlicensed medicine and 100,000 fake pills. Almost 1,300 UK-based websites were shut down.

In France, customs seizures almost doubled compared to the Pangea V operation from 427,000 medicines seized more than 812,000, including more than 668,700 in Roissy Airport. Among the seized medicines, French Customs have counted 155,000 counterfeit pills which much of doping products and over 429,000 medicines without an authorization for placing on the market. 144 illegal e-commerce sites of medicinal products have been identified, of which 29 linked to France.

Each EU State members participating to this operation were in the same situation. However concerning Poland, the Pharmaceutical Security Institute reported that there were more than 30 incidents of counterfeit medicines in 2012, the fifth highest number in the EU. Poles spend roughly $32 million a year on fake medicines.

The most frequently counterfeited medicines are impotence medicines and anabolic supplements, diet pills, and psychoactive medicines. Most “fillers” in these medicines are safe placebos like sugar, but some pills have contained anti-freeze, wood polish, plaster, amphetamine, lead and other dangerous compounds.

\(7\) Consequently to the judgment of the EU Court of Justice (1 December 2011) related to the joint cases Nokia and Philips, and in the light of certain cases of customs detentions on the grounds of patent infringement of shipments of medicines originating in a third country, it is understood that the mere fact that medicines are in transit through the EU territory, and there is a patent right applicable to such medicines in the EU territory, does not in itself constitute enough grounds for customs authorities in any Member State to suspect that the medicines at stake infringe patent rights. 3 It is further understood that a situation in which medicines are in transit through EU territory, and there is adequate evidence that satisfies the customs authorities that there is a substantial likelihood of diversion of such medicines onto the EU market, may constitute enough grounds for customs authorities to suspect that the medicines at stake infringe patent rights.

\(8\) Supported by the Permanent Forum of International Pharmaceutical Crime, the Heads of Medicines Agencies Working Group of Enforcement Officers, the Pharmaceutical Security Institute, and supported by the Center for Safe Internet Pharmacies and private sector companies including Visa, MasterCard, PayPal and Legitscript.
The Eastern Europe illicit pharmaceuticals market

The pharmaceutical market is affected by the financial crisis in that it is exerting upward pressure on medicine prices. In Lithuania, price rises are linked to VAT increases. Kazakhstan, the Republic of Moldova and Ukraine report pharmaceutical price increases of up to 30%. The general upward pressure on prices across the Region is exacerbated by country-specific currency depreciations, as in the case of Armenia. This pricing policy inevitably leads to resurgence in illicit trafficking, given the lack of protection against this kind of overspill.

Concerns about the effect of the crisis on the utilization of care are only now emerging. In Italy, the risk of excluding patients from dental care that traditionally comes with high levels of user charges and correspondingly heavy financial burdens on household budgets has led to a regional initiative to protect dental care for vulnerable population groups. In the eastern part of the European Region, there are substantial concerns about increases in the price of health services and pharmaceuticals. In Ukraine during first two months of 2009, for instance, health service prices increased by more than 30% compared with the same period in 2008 Price increases have a considerable effect on private health expenditures (in the form of official user charges and co-payments, payment for medicines, or informal payments) in numerous countries in the Region, and it is feared that this may deter patients from seeking the necessary care as it becomes unaffordable, who may turn to illegal services and online purchases. Even before the crisis, in 2005 WHO recorded private health expenditure as accounting for more than 50% of total expenditure in Albania, Armenia, Azerbaijan, Cyprus, Georgia, Greece, Kyrgyzstan, Tajikistan and Uzbekistan. In December 2008, Lithuania removed the VAT rate of 5% on pharmaceuticals. Medicines are now taxed at a standard rate of 19%, leading to a close to 14% increase in pharmaceutical prices and a 10% increase in health care expenditure as compared to December 2007. In Armenia, Consumer price inflation in 2008 stood at 9%, a relatively high level, but dropped to 5.3% at the end of the year. However, in early March 2009, Armenia abolished the fixed exchange rate for the Armenian dram and introduced a floating rate. This led to an immediate increase in prices of commodities such as oil and food of between 20 and 30%. This explosion in prices now also affects essential medicines such as antibiotics or vaccines, to the great delight of the local mafias.

Eastern European countries are believed to be both major sources and consumers of counterfeit medications. Legal penalties in the region vary from country to country, with higher legal penalties in countries such as Russia and weaker legislation against fakers in countries like the Czech Republic and the Ukraine. Despite strict penalties, Russia remains a major producer of counterfeits for the entire European region. Some countries in the region, such as Belarus and Hungary, have seen a significant decrease in the prevalence of counterfeits in recent years through increased surveillance efforts and stricter import and regulatory laws. Medicines most commonly seized in the region include lifestyle pills like anti-impotence medicines, vitamins, and diet pills, as well as life saving medication such as anti-stroke pills, antibiotics, and cardiovascular medications. According to one report, more than 20% of the pharmaceutical market value in many of the former Soviet republics is consumed by counterfeit medicines, which is close to levels found in poorer developing countries.

About the Russian Federation, The increase in spending on health, amid the current crisis, affects the most vulnerable sections of Russian society. “A distinction must be made between normal increase, due inflation and the weakening of the rouble, and the current increase, which I believe, is nothing more than an attempt to make money on the backs of the people”, declared two years ago President Dimitri Medvedef.
Since the beginning of the year 2012, the price of medicines exploded: 11% growth in three months, compared with 14% for the whole of 2008. A tube of aspirins, whose wholesale price has gone from 2.75 to 5.5 roubles, is sold at 8 to 10 roubles in pharmacies. The wholesale price of a box of Mezim-forte, treating digestive problems, has increased by 24 roubles, bringing the retail price up to 200 roubles.

The economic crisis, the decrease in Russians’ purchasing power, the increase in the price of medicines, the weakness in the medicine control system, the mass industrialization of generics, all contribute to the strong development of pharmaceutical counterfeiting in Russia.

The problem of counterfeit medicines is a thorny and sensitive issue in Russia. It has even become a priority for the government and many healthcare professionals. According to certain Russian surveys, around 40% of the population of the Russian Federation think that they will take counterfeit medicine at some point. It is therefore evident that the rapid implementation of decisive measures is essential.

On 3 June 2012, a round table was held in the Russian Federation Council. The participants decided to form a task force responsible for developing proposals for the amendment of existing laws, which had little deterrent effect and were ineffectively enforced. On of the most important member of the Social Policy Commission of the Federation Council said that pharmaceutical counterfeiting causes a lack of confidence in the entire Russian health system among the population, and that fakes have serious health consequences on many patients. In addition, this situation raised doubts over the integrity of Russian industries involved in the production and sale of medicines.

The vice-president of the commission on healthcare protection of the Duma also confirmed that 12% of counterfeit medicines were sold in pharmacies within official distribution circuits. According to his experts, solving this problem requires the rapid implementation of three measures: making health professionals accountable for medicinal practices, developing a health insurance system that provides more protection, and introducing a law requiring transparency in the production and sale of medicines.

On the following 6 June 2012, a meeting was organized at the RIA Novosti headquarters. Russia experts stressed that the problem of counterfeit medicines had to be dealt with at an international level, considering that this counterfeiting is closely linked to Chinese criminal networks exporting illicit products. They declared, among other things, that nearly 30% of counterfeit medicines come from abroad and that the remaining 70% are manufactured in the Russian Federation.

**About the Czech Republic**, According to reports, the most commonly counterfeited and illegal medicines are erectile dysfunction medicines, anabolic steroids and weight-loss medicines. In March 2012, Czech customs officers seized 5,200 tablets of counterfeit Viagra and Cialis, worth over $105,810, in a parcel from India - the largest consignment of this kind in several years. In July 2012, customs officials in Kralupy and Vlatou destroyed one ton of fake medicines. Authorities also discovered approximately one million pills intercepted in the mail mainly coming from China and India.

According to the Czech State Institute for Medicine Control (SUKL) statistics, roughly 11% of people in the Czech Republic bought medicines over the Internet in the recent past. Under Czech law, however, only over-the-counter medicines can be sold over the Internet and only by registered pharmacies holding a license for the web sale, while prescription medicines must be picked up in pharmacies. Nevertheless, 50% of medicines offered on suspicious websites in the country are estimated to be fake.
**About Ukraine.** The limited information available on Ukraine suggests that the prevalence of counterfeit medicines is between 20% and 40%, with some reports claiming that the percentage in certain medicine classes may be as high as 80%. If such a high rate is correct, it is probably due to a general lack of control over the import and distribution of pharmaceutical products in the country, despite national legislation for the control of the pharmaceutical market.

It is likely that counterfeits have permeated Ukraine’s domestic market through its long, shared border with Russia.

Ukraine, like many other Eastern European countries, does not currently consider counterfeiting medicine a criminal offence. While medicines can be seized from chemists and hospitals if they constitute a health risk for Ukrainians, their producers and importers cannot be prosecuted under the current legal structure.

**United States of America and Canada**

In 2009, the United States spent 2500 billion dollars on health, approximately 17.6% of the gross domestic product (GDP). In terms of the US population, this figure represents more than 8000 dollars per inhabitant per year. Despite this significant health budget, the United States has worse results that most other developed countries in terms of average life expectancy: 79 years in 2009, compared to 80 or more for most Western and Northern European countries, 81 in Canada, 82 in Australia and 83 in Japan. The United States are aware of the discrepancy between the financial resources used and the results obtained in terms of health.

The figures published in February 2011 by the Agency for Healthcare Research and Quality show significant differences between the availability and quality of health care depending on different socio-economic factors, in particular ethnic origin and income. These figures show that the different ethnic groups (blacks, Asians, Hispanics and native from America and Alaska) receive a lower quality of health care than the reference group (whites) in 20% to more than 50% of cases, and have greater difficulties in accessing healthcare in 20 to 80% of cases. Such disparities are even more obvious when comparing different social classes: more than 80% of criteria show that the poorest social classes (with incomes falling below the federal poverty level) receive a lower quality of healthcare than wealthy groups (income four times higher than the federal poverty level) and 100% of the criteria show that the poorest social levels have less access to healthcare. Geographical and demographical criteria also play an important role in the access to and the quality of healthcare. A national study showed the differences that exist in these respects between different States. Apparently, West Coast states and New England score higher marks than the Central States. Demographics also play a role in access to and quality of healthcare: there are differences between the populations living in major cities (more than 1 million inhabitants), medium cities (250.000 to 1 million inhabitants), small cities (50.000 to 250.000 inhabitants) and the populations living in “micropolitan” areas (town and villages of 10.000 or 50.000 inhabitants) or in rural areas. If the populations living around major metropolitan areas are taken as a reference (as these are generally the least affected by poverty and healthcare access problems), it appears that the populations living in the centre of large cities, in “micropolitan” areas and in non-urban areas are the worst off in terms of healthcare quality and access.

With weak healthcare coverage, many people refuse to sign up to supplementary health insurance. For more than 40 million poor American residents (14% of the total population of the US), access to medicines is problematic. The counterfeit market was therefore quick to take up roots in North America. The US government has been trying to find measures to control this problem since the early 2000s.
The United States is currently processing hundreds of cases of counterfeit medicines from Mexico and Canada. The Internet is also becoming a subject of great concern due to its uncontrolled use by 40 million patients unable to pay for their health expenses. The Medicine Enforcement Administration (DEA) and the FDA are concerned, among other, by the abundance of publicity links on Internet search engines advertising potentially counterfeit or dangerous medicines. The publicity is generated by laboratories based abroad that are not subject to US federal law. Since the end of 2008, the United States has registered a number of deaths of people that ordered and took medicines without medical prescription. The International Narcotics Control Board (INCB)-based in Vienna, Austria which published its annual report in September 2009, states that in the United States, for one, pharmaceutical counterfeiting is becoming more dangerous than heroin and cocaine. It estimates that the abusive use of prescription medicines has already eclipsed traditional illegal medicines such as heroin, cocaine and ecstasy. The report states that the abuse and the traffic of medicines is going to overtake the consumption of narcotic medicines. Demand for these products is so strong that it has given birth to the new phenomenon of counterfeit medicines and progress made on the control of narcotics over the last forty years are being undermined. Thus, the United States is seeing a significant increase in the abuse of painkillers among adolescents and students. Their counterfeits have made their appearance in North America, especially a copy of Subutex sold online and re-exported illegally via France. The abuse of anorectics - substances to help people lose weight - is also becoming a problem, with risks of addiction through excessive consumption.

Recent statistics from the United States of America do not seem enough to draw a good balance. The finding figures provided by The Counterfeit Pharmaceutical Inter-Agency working group, the Office of the Intellectual Property Enforcement Coordinator, Food and Medicine Administration, U.S. Customs and Border Protection, U.S. Immigration and Enforcement Customs, the Departments of Justice, Commerce and State, the Agency for International Development and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), do not be reconciled. So, to avoid any error, we have just worked on the only figures of U.S. Customs and Border Protection.

Globally, in 2012, US Customs and Border Protection seized 2350 pharmaceuticals estimated about $82,997,515: 35% decrease compared to 2011.

In the same time, Operation Pangea V resulted in 79 arrests and the seizure of 3.7 million doses of potentially life-threatening counterfeit medicines worth an estimated value of $10.5 million.

In 2013, the action occurred as part of the 6th annual International Internet Week (from June 18 to June 25) of Action (IIWA), a global cooperative effort to combat the online sale and distribution of potentially counterfeit and illegal medical products. As part of this year’s international effort – Operation Pangea VI – the FDA’s Office of Criminal Investigations, in coordination with the United States Attorney’s Office for the District of Colorado, seized and shut down 1,677 illegal pharmacy websites.

Many of these websites appeared to be operating as a part of an organized criminal network that falsely purported its websites to be “Canadian Pharmacies.” These websites displayed fake licenses and certifications to convince U.S. consumers to purchase medicines they advertised as “brand name” and “FDA approved.”

9The FDA did not grant us access to the latest figures but recognized that the courts were currently processing hundreds of cases for 2009 alone, without specifying whether these concerned patent violations or potentially dangerous counterfeits.

10This independent legal organization, made up of 13 members- doctors, pharmacologists and experts- and created in 1968, has been appointed by the UN to supervise the implementation of international conventions on the control of narcotics.
The medicines received as part of Operation Pangea were not from Canada, and were neither brand name nor FDA approved. These websites also used certain major U.S. pharmacy retailer names to trick U.S. consumers into believing an affiliation existed with these retailers.

As compared, in Canada this year, the Royal Canada Mounted Police (RCMP) and Canada Border Services Agency (CBSA) joined forces with INTERPOL to inspect 3,444 packages originating from 19 countries. Of these, 3,223 packages, which contained 238,820 illicit and fake medicines at a street value of $1.032,514.00 CAD, have been seized. “These seizures represent a small fraction of the counterfeit medications that are available in our country. This is the harvest of one week out of fifty-two, and in Canada only” said RCMP Commissioner Bob Paulson.

In synthesis, counterfeit, gray, and substandard medicines pose an unequivocal threat to the public health of North Americans. The US Food and Medicine Administration (FDA) reports the number of counterfeit medicine investigations have grown almost ten-fold in the last five years. Although the Agency estimates that less that 1 percent of medicines on the US market fall into one of these illicit categories, this could still mean that there is as much as a 1-in-100 chance of obtaining an illicit product. This also means that of the 4 billion prescriptions filled in the United States each year, as many as 40 million may be filled with counterfeits. This astonishing figure does not account for the growing number of incidents involving gray area pharmaceuticals originating in North America itself, which can cause similarly damaging effects to human health and security.

Latin America

Latin America currently ranks second behind Asia as having the highest number of counterfeit medicine “incidents,” report professional associations like the Pharmaceutical Security Institute (PSI). Fake medications have been identified in Argentina, Mexico, Brazil, Panama, Peru, Ecuador, Bolivia, Paraguay, Uruguay, Venezuela, Colombia, and Belize.

In 2012, the Caribbean Poison Information Network estimated the value of the counterfeit medicines trade in Latin America and the Caribbean to be around USD 30.5 billion.208 According to the available data, medicines commonly counterfeited in Latin America include antibiotics, anti-impotence medicines, flu medications, anti-allergy pills, analgesics, and medicines such as Lipitor, used for the treatment of high cholesterol. Information on substandard medicines in the region is minimal, though substandard products - including expired and adulterated medicines - have been reported.

The counterfeit medicine industry in Latin America has attracted the attention of organized criminal groups in the region, including Colombian cocaine traffickers and the Mexican mafia, particularly in environments of weak regulation and enforcement, where potential penalties are minimal compared with potential profits.

In details, our data collection can check the following information:

- El Salvador’s Association of Pharmaceutical Companies (INQUIFAR) reports that there is a widespread availability of counterfeit medicines on the domestic market. According to the local manufacturer Gamma Laboratorios, the commercialization of counterfeit medicines generated economic losses of around $40 million to the country’s pharmaceutical industry that year.
- Mexico’s pharmaceutical industry, a US$15.5 billion market, is plagued by widespread and complex problems, including counterfeit medicines, theft, and irregular sales practices. In 2012, illicit activity amounted to roughly US$2 billion, or 14%, of the formal market, and counterfeiting represented 81% of the illicit market. The two most popular types of counterfeiting in the Mexican market are: (1) partial or total active product
ingredient substitution, which can create medicines that are sub-potent and/or laced with hazardous materials, and (2) “recycling” of expired medications, in which organized crime rings repackaged and redistribute medicines that have gone bad. This illicit practice is possible because Mexico lacks a formal waste management system for expired pharmaceuticals.

- An estimated 22,000 Argentineans die each year as a result of consuming counterfeit and adulterated medicines, according to an official report of the Argentine Union of Pharmacists and Biochemists. The report also claims that 10% of medicines in Argentina are fakes, in contrast with the National Medicine and Technology Agency (ANMAT) figure, which is less than 1%. The counterfeit medicine trade in Argentina is a serious, systemic problem in which leaders in politics, business, and labor all participate. An official probe into counterfeit medicines in the Buenos Aires region began in 2007, when the recently appointed Minister of Health of the Nation, Graciela Ocaña, launched an investigation into more than 400 complaints from the State that had been collected since 1995 regarding reports of counterfeit medicines and forged documents found in various pharmacies. Federal Judge Norberto Oyarbide ordered a number of raids and arrests in relation to the case. In November 2009, 155 establishments were raided and five arrests were made. In September 2010, a raid of the Bank Clerks’ Union Hospital led to the seizure of expired medicines and evidence of counterfeit transactions among a number of other workers unions. In November 2010, Oyarbide ordered 42 raids in five Buenos Aires neighborhoods, and seized documents that show evidence of trade in counterfeit medicines for cancer, AIDS, and hemophilia. In December 2010, a raid was conducted at the APE offices in the Ministry of Health headquarters, and seized files indicating pharmaceutical providers had presented false vouchers and medicines to receive reimbursements. As of February 2011, over 50 workers unions, as well as a number of medicine distributors and former politicians, were under investigation. In 2012, the economic impact of illicit medicines in Argentina should be US$ 70 millions minimum.

- **Bolivian authorities** seized more than 40 tons of counterfeit, expired and/or adulterated medicines between December 2009 and January 2010. Many of the medicines were seized from a local importer called Eske SRL had expired and were relabeled with new use-by dates. The head of Eske SRL, as well as the head of another company that was found to be producing counterfeits, faced prosecution for crimes against public health that carry a penalty of up to seven years jail. Following the seizures, authorities visited 200 pharmacies within a 48-hour period in January 2010; 26 were closed down and 74 set to be fined. Estimation of economical impact of counterfeit medicines is difficult.

- **In Brazil**, the main counterfeit medicines seized by the Federal Police between 2007 and 2010 were medicines against erectile dysfunction and anabolic steroids. These data confirm the information released by ANVISA that the counterfeit medicines with the largest number of seizures in Brazil over recent years belong to these therapeutic classes. This can be explained by the greater demand for these pharmaceutical groups among the Brazilian population and by their high prices. The Brazilian states that presented the greatest quantities of counterfeit medicines seized by the Federal Police were in the southern and southeastern regions, which are affected by trade in counterfeit products. The port of Santos, where such medicines may enter Brazil, is located in the state of São Paulo. Paraná is located in the region of the triple frontier (Argentina, Brazil and Paraguay), which makes it possible for these medicines to come from Paraguay, a country with a vast culture of counterfeiting foreign products, with less rigorous legislation and supervision and with lower prices. Santa Catarina has a border with Argentina, which may also be an entry route for such products.

The hypothesis that a large proportion of the counterfeit medicines seized by the Brazilian Federal Police are produced abroad and enter the country through its ports and across its borders is reinforced by the fact that a large proportion of the counterfeit medicines analyzed by the Federal Police were seized together with smuggled foreign medicines, mainly of Paraguayan origin. The results from this data collection reflect the
real dimensions of the problem of medicine counterfeiting and smuggling in Brazil, as shown by the huge increases in the number of seizures made by the Federal Police every year. Unfortunately, the only one acceptable study giving an idea of the Brazilian situation is a retrospective descriptive study on expert reports (Rev. Saúde Pública vol.46 no.1 São Paulo Feb. 2012 Epub Jan 06, 2012) produced by criminal investigators of the Federal Police between January 2007 and September 2010, in relation to counterfeit medicines. For the authors, Joseane Ames and Daniele Zago Souza, the medicines with greatest numbers of seizures were selective phosphodiesterase-5 inhibitors that are used for treating male erectile dysfunction (Cialis® and Viagra®, mean about 66%), followed by anabolic steroids (Durateston® and Hemogenin®: 8.9% and 5.7%, respectively). The greatest proportions of the counterfeit medicines were seized in the states of Paraná, Santa Catarina (both Southeastern Brazil) and São Paulo (Southeastern), and the number of non-authentic medicines sent for investigation increased by more than 200% over the study period. There were increases in seizures of smuggled medicines found together with counterfeit medicines: 67% of the seizures included at least one smuggled medicine.

- **Colombia** has a known problem with not just counterfeits, but substandard medicines as well. In 2007, 43 lots of medicines, from analgesics to antidepressants, failed to meet quality standards and were destroyed. 314,827 samples from 43 local and 17 multinational companies were analyzed. Of those samples, 2.3% failed because of storage or transportation problems, which affected the medicines’ quality, and 4.1% failed because of non-compliance with manufacturing standards. This situation is unfortunately usual in this country.

In 2013, it is increasing. The counterfeit pharmaceutical trade in Colombia could be as profitable as the illegal medicines market, according to Colombia’s customs chief, illustrating how organized crime groups are taking advantage of a growing global enterprise thought to be worth billions of dollars.

In the last year and a half, Colombian authorities have seized more than five million units of counterfeit medicines intended for resale, worth a total of more than $2 million. Gustavo Moreno, director of Colombia’s tax and customs police, said profit margins were between 500 and 1000%, making the trade potentially as lucrative as selling illicit medicines. These counterfeit medications fall into two main categories: contraband and fake. Contraband medication is typically sold under a false label or past its expiration date. Fake medicines, are usually medicine packaging filled with anything from flour to cement. Both have potentially deadly effects. According to authorities, Panama, Venezuela, Ecuador and Peru are the main countries of provenance for illegal pharmaceuticals trafficked into Colombia. The medications arrive hidden in shipments of other imported goods, usually through La Guajira, Norte de Santander, Nariño, Choco and Valle departments. They are then commonly distributed to shops in "San Andresitos" -- shopping areas offering contraband at heavily discounted prices.

- **Paraguay**’s Prosecutor General, Javier Díaz, has warned that counterfeit medicines controlled by organized crime are endangering lives, shedding light on a lesser-known criminal enterprise thought to be worth billions of dollars globally. For 2012, the turnover of counterfeiting market is about $12 billion. However, it is impossible to identify the estimated amount dedicated to counterfeit medicines. Trademark infringement and counterfeiting are serious problems. Owners of patents, trademarks, and copyrighted materials are advised to register their products with the Industrial Property Office in the Ministry of Industry and Commerce. Paraguay is recognized as a regional distribution and manufacturing center for counterfeit merchandise. The re-export trade to Brazil, catering to consumer demand. Multinational pharmaceutical and agrichemical producers complain that the government does not safeguard confidential marketing and test data that businesses are required to submit in the product registration process.

- **About Peru**, the percentage of counterfeit medicines relative to the total medicines
The impact of counterfeit or falsified medical products can be both direct and indirect. Health effects on patients can be described as “inconvenient”. But increasingly some counterfeit life-saving medicines, such as antimicrobials, signifies a serious public health threat. In 2013, according to Peru’s Association of Pharmaceutical Laboratories (ALAFARPE), the amount of counterfeit medicines should be about $46 million.

Venezuela, the third-largest pharmaceutical market in Latin America, has experienced consistent double-digit growth in recent years. Access to healthcare is guaranteed by the Venezuelan constitution, and the government has used revenues from its oil industry to invest in healthcare. However, the Venezuelan market presents formidable barriers to foreign manufacturers of branded medicines—an extremely difficult financial environment, weak intellectual property protection, limited coverage of innovative medicines, a price freeze and new price controls, and a governmental focus on developing a strong domestic pharmaceutical industry and working with key international allies. It is estimated that one in four pharmaceuticals is a counterfeit or fails to meet regulatory standards.

Asia

Estimates of the economic scale of counterfeiting in Asia are difficult to quantify. The economic burden of medicine counterfeiting is continuously increasing. Although counterfeit medicines have been distributed through every economy, Asia is reported to be the largest source of pharmaceutical crime.

Most literature derives from local investigative journalism with little scientific public health inquiry relative to the enormous scale of this criminal enterprise. Estimates put the total loss of life to counterfeit pharmaceuticals between 500,000 and 1 million people each year (Kafchinski, 2009).

Counterfeit or falsified medications can lead to varying degrees of effectiveness and danger. For some counterfeit life-style medicines, such as medications to treat erectile dysfunction, the health effects on patients can be described as “inconvenient”. But increasingly counterfeit medicines in Asia are not just “lifestyle” medicines but widely used medicines such as those for cholesterol or high-ticket items such as cancer medicines.

The impact of counterfeit or falsified medical products can be both direct and indirect. Patients who take disease prevention medicines may end up getting sick when they believed they were protected. They may not recover from illness as quickly as they would have with legitimate products.
medicines, or may not recover at all. In 2008, the WHO calculated that out of one million people dying every year from malaria, 200,000 deaths could be avoided if anti-malarial medicines were effective, of good quality and used correctly. Recently the Fides Agency reported that, according to the WHO, about 700,000 people die each year due to counterfeit medicines for malaria or tuberculosis (Akunyili, 2011).

Patients who take counterfeits fail to get better and lose faith in the effectiveness of modern medicine. In Asia where complementary medicine is widespread, patients may turn instead to traditional or herbal medicine. Counterfeit or falsified medicines may create the wrong impression that the medicines themselves are ineffective and, thus, lead prescribers to unnecessarily opt for others as their first line treatment. New medicine development may be required in response to “ineffective medicines”, which will be more expensive and will further disadvantage patients in developing countries.

It was often assumed that the active ingredients or excipients within counterfeit medicines in Asia are inert. However, forensic chemistry has demonstrated that many contain ingredients that are harmful as tragically demonstrated in Singapore where glyburide, a powerful medicine used for the treatment of diabetes, was found to be a contaminant in counterfeit tadalafl and herbal preparations for treatment of erectile dysfunction. Of the 150 non-diabetic patients admitted to hospitals in Singapore, seven patients were comatose as a result of severe neuroglycopenia and four patients subsequently died (Cheng, 2009). In Taiwan, 650000 fake diet capsules and 240kg of raw materials were seized after receiving complaints from the public of palpitations and dizziness after consuming the capsules. The capsules were found to contain phenolphthalein, a cancer-causing organic acid that has been banned since 2001.

Perhaps one of the most worrying implications of the global boom in counterfeit medicines is the acceleration of new, medicine-resistant strains of viruses, parasites and bacteria. Counterfeit medicines for infectious diseases containing too little or sub-therapeutic amounts of active ingredients destroy the clinical efficacy of the genuine medicine by promoting medicine resistant pathogens, a phenomenon observed with malaria medicine resistance in South-East Asia. In 2012, the Oxford University experts reported in the British Medical Journal that 38%-53% of vital anti-malarials obtained from pharmacies and shops were counterfeit. Samples were taken from Cambodia, Laos, Myanmar (Burma), Thailand and Vietnam. A more recent study discovered a much higher number: 68% of artensunate medicines collected did not contain correct amounts of active ingredient. In Burma, for example, counterfeit artesunate samples, were found to have between 3.5 and 12.1mg of artesunate per tablet, less than one fifth the amount in a standard authentic tablet. Plasmodium falciparum artesunate resistance has been recently described on the Thailand-Cambodia border probably as a result of counterfeit artesunate.

China

The Washington-based International Policy Network identifies China, like India, as the world’s biggest sources of counterfeit medicines. China, periodically, announces crackdowns on counterfeiters or makes big sweeps in which it arrests dozens, or even hundreds, of suspects. In separate events last year, it reported shutting down hundreds of manufacturing facilities making counterfeit medicines and toxic medicine capsules. It is at it again, with the State Food and Medicine Administration (SFDA) saying it has a 6-month campaign to stop medicine and traditional Chinese medicine counterfeiters and online retailers of counterfeit. According to Reuters, there were few details and no mention of regulation changes - only the pledge to stop offenders "We must resolutely punish illegal acts, expose illegal enterprises, recall problematic products," Wu Zhen, the agency’s deputy commissioner, said in a statement. Whether this is something more serious than earlier efforts has yet to be seen. In a major display of action last August 2013, 18,000 Chinese police officers executed the roundup of nearly 2000 medicine
counterfeiting suspects and destroyed 1100 production plants. In the first 7 months of 2013, police in China conducted over 19,000 anti-counterfeiting cases throughout the country. The Ministry of Public Security reported that the counterfeit products seized and destroyed by security forces included. The fake medicines, valued at $182 million, were advertised for everything from hypertension to cancer and rabies, authorities said.

If the situation is worrying for countries importing Chinese medicines, on the Chinese population itself is even more alarming. Counterfeit medicine is having a tragic impact in China. Due to privatization and modernization of healthcare, the health industry is starting to offer various levels of private medical services. Because people are becoming wealthier, the expectation for higher-quality medical services will also likely rise. The Chinese people's growing wealth and expectations is giving the government concern because officials are expecting a 120% increase in demand for basic medical services. Officials are troubled that the rural population, which represents 70% of China's total population, only receives 20% of public spending on health, and may suffer disproportionate access to health care. Moreover, when 20 million urban residents and 30 million rural residents remain at the State’s absolute poverty line, this causes great concern about the availability and accessibility to medicine. With 60 million rural residents who are barely able to dress warmly or afford enough to eat, one can only imagine what access they would have to medicine. Indeed, one can easily understand why the poorest Chinese would be most susceptible to buying counterfeit medicine when sold at a discount compared to the genuine product. This disparity in wealth means there is a growing sector of the population who is wealthier and demands higher quality, more expensive name brand medicines. However, there remains a large portion of China’s population, who cannot afford name brand medicine, and these people are likely to turn elsewhere in search of the "richman’s" medicine.

There is also an increasingly large elderly population that will be seeking name brand medications. In 20 years, there will be more than 170 million people over the age of 60 in China, increasing the number of patients who might suffer from chronic diseases and demand more medication. Add to that the growing number of AIDS patients, which China currently estimates at one million; 134 this number is expected to increase 30 percent annually and reach 10 million by the end of the decade. China quite possibly may have a severe crisis on their hands.

Attempting to provide more health coverage, the government’s response has been to pledge $10 yuan ($1.20 USD) per year into the medical accounts of each rural resident as part of its Social Insurance system.

However, with the high cost of name brand medicine, no doubt many Chinese will find counterfeit medicine more obtainable for their ailments. Counterfeit medicines have reached greater numbers of Chinese; Just for not forgetting, in 2001 alone, more than 192,000 people in China died from using fake or poor quality medicine. These figures illustrate that using medicine containing substances made of anything from chalk dust to fruit peels means that these counterfeit “cures” can be as deadly as the diseases themselves.

About AIDS treatment, as China is now just beginning to deal with its AIDS epidemic, the counterfeit medicine market poses a serious problem in terms of counterfeit AIDS medication. “One of the things we are going to see, very surely, is a lot of these bogus [AIDS] medicines will be in the slipstream . . . . The market will be flooded with these for sure,” states Richard Feachem, former Executive Director of Global Fund to Fight AIDS. AIDS treatments are expensive, and China has a population that must now deal with AIDS treatments. Counterfeiters have proved that they are very adept at mastering even the most complicated packaging and can capitalize on a growing trust in Western medicine. There are even reports in Beijing of counterfeiting medicines claiming to cure SARS. With China’s history of counterfeiting and the growing number of
counterfeit medicines, China will face a dilemma of trying to provide quality medical care as well as trying to change the Chinese way of thinking that counterfeits are a cheaper, and therefore better, version of the real thing.

About accessible medicine, Viagra was for a long time the most popular counterfeit medicine in China. Reports indicate that each year, more than one million counterfeit Viagra tablets are seized. A growing trend in China is the selling of fake medicines in sex shops. Because sex is still sometimes a taboo subject for many men, many would rather go to a sex shop to purchase medicine touted to cure sexual dysfunction than see a doctor. With longer business hours, including some stores open 24 hours, these sex shops offer quick and easy access whereas getting these pharmaceuticals through hospitals is more time-consuming. In hospitals, patients must make an appointment, talk to a doctor, and have their sexual dysfunction noted on their permanent medical chart. However, shopping for medication at these shops spells danger for the average consumer. A recent survey cited that of the more than 95 percent of sex shops in China selling medicine to cure erectile problems, half of them receive revenue from counterfeit medicinal products. Because Chinese consumers can easily obtain counterfeit medicine from such shops or obtain undetectable counterfeit medication from hospitals, the consequences are troubling.

India

The world’s largest manufacturer of generic medicines has become a busy center for counterfeit and substandard medicines. Stuffed in slick packaging and often labeled with the names of such legitimate companies as GlaxoSmithKline, Pfizer and Novartis, the counterfeit medicines are passed off to Indian consumers and sold in developing nations around the world. Experts say the global fake-medicine industry in India, like China, is contributing to a rise in medicine resistance. Estimates vary on the number of these medicines made in India. The Indian government says that 0.4% of the country’s medicines are counterfeit and that substandard medicines account for about 8%. But independent estimates range from 12 to 25%. In the other hand, the Federation of India Chambers of Commerce (FICCI) claims that 15-20% of medicines on sale in India are counterfeit.

However, Indian officials acknowledge the clandestine industry has hurt the image of India’s booming pharmaceutical industry and its exports, worth $8.5 billion a year, mostly to African and Latin American countries. To clamp down on the illegal trade, the health ministry launched a reward program during 2010 offering $55,000 to those who provide information about counterfeit medicine syndicates. In 2009, the ministry also strengthened its medicine law to speed up court trials. Suspects found guilty of manufacturing and selling fake medicines can be sentenced to life for a long term in prison. However, It is very difficult to dismantle criminal networks. When authorities bust one operation, two more spring up elsewhere.

But more than the concern for public safety, officials here have been particularly alarmed about last two years incidents that discredit India’s image abroad. For example, In June 2011, officials at Nigeria’s Abuja airport caught a shipment of fake antibiotics, containing no active ingredients, with a "Made in India" label. Nigerian investigators later said that a Chinese company shipped the medicines via Frankfurt. In a similar incident, a shipment of fake anti-malaria medicines from China arrived in Nigeria with an Indian tag. Likewise, in 2012 Sri Lanka banned imports from four Indian companies after officials discovered substandard medicine in shipments. Over the years, pharmaceutical industries have used holograms, embossed their logo on the packaging or used other brand protections, but these have also been counterfeited in India.

Many Indian companies are apprehensive of pursuing the cases for fear of bad publicity and possible loss of confidence among patients.
Prevalence of counterfeit medicines in other countries of South East Asia (2012 statistics)

In Malaysia, according to the Ministry of Health studies, 5.2% of medicines sold over the counter are counterfeit, confirmed by the Think Tank Emerging Markets Health Network (EMHN) and the Pharmaceutical Association of Malaysia. They pointed that in October 2012, Health Director-General Datuk Seri Dr Hasan Abdul Rahman said the Medicine Control Authority (DCA) had cancelled registration of the product MYMEN PLUS capsule 400mg last September 27 because it contained a type of scheduled poison known as tadalafil. Usage of tadalafil without proper diagnosis and monitoring by a doctor can cause serious problems, such as loss of vision and/or hearing, lower blood pressure to a dangerous level drastically, and can affect the cardiovascular system, causing stroke and heart attack. Usually, Tadalafil is in the treatment of erectile dysfunction and can only be supplied by doctors or pharmacies upon doctor’s prescription. The DCA also advised against using another traditional medicine, Jin Fei Cao San Extract Powder “SHENG CHANG” to treat the common cough and cold. The medicine was found to contain scheduled poison, ephedrine and pseudoephedrine that could lead to hypertension and psychiatric-related symptoms if used indiscriminately. Generally, on counterfeit medicines, according to the EMHN’s paper, such producers have evolved from basement operations to manufacturing on an industrial scale. A divers range of players are involved in their manufacture and distribution, including medical professionals, criminal groups, rogue local pharmaceutical companies, corrupt government officials and terrorist organizations. In Malaysia, producers and purveyors of fake medicines are exploiting the increasing globalization of the pharmaceutical supply chain, poorly defined and enforced civil and criminal laws, and a lack of an international definition of what legally constitutes a fake medicine. Most academics and NGOs prescribed a mixture of stronger regulation, but for EMHN, the creation of new regulatory layers and tougher criminal sanctions may be counterproductive, especially because new powers for regulators create opportunities for bribery and corruption.

A study from Alter Hall throughout Laos, Myanmar, Vietnam, Cambodia found that 68% of artesunate (anti-malaria) medicines did not contain the correct amount of active ingredient. 22% of sample of Antibiotic in Laos had incorrect levels of active ingredient. About anti-malaria approach, the anti-malaria counterfeit medicines distributed in the Greater Mekong Subregion (GMS) are a dramatic problem. A critical component of addressing artemisinin resistance in the GMS over the past decade has been the move to eliminate oral artemisinin-based monotherapies and to address the problems of substandard and counterfeit medicines (SCMs), which remain a regional public health concern. Counterfeit medicines are responsible for loss of life and substandard medicines (genuine medicine products with specifications outside the authorized and specified standards, e.g., insufficient quantities of the active ingredients) may contribute to antimalarial medicine resistance as the parasite may still survive and develop resistant strains (WHO, 2009). In May 2007, the World Health Assembly issued a resolution for a ban on artemisinin-monotherapies and governments of the Mekong countries have been working towards elimination of these medicines, with different degrees of success. A huge amount of work to combat the supply and distribution of SCMs has occurred in the GMS over the past decade. In 2002, a medicines quality-monitoring network was established to regularly collect samples of antimalarial medicines in selected provinces in all 6 countries (Delacollette et al., 2009). The rate of progress to set up or consolidate quality monitoring mechanisms and action backed up by National Medicine Regulatory Authorities has been quite different in each Mekong country and remains a challenge. The set up of the monitoring network was followed by the establishment of an international multidisciplinary group in 2006-2007, which conducted a joint investigation on counterfeit artesunate in the Mekong countries.
This group comprised WHO officials, doctors, scientists, United States Pharmacopeia Medicine Quality and Information program and INTERPOL. A sample of 391 artemisinin tablets collected between 1999 and 2006 in the 6 countries showed a wide variety of fake artemisinin, claimed on label as manufactured in China. Evidence was presented to the Chinese authorities who conducted a criminal investigation of the manufacturing sites and subsequently made arrests (Newton et al, 2008).

Cambodia has taken the lead issuing a ban in 2008 on all oral artemisinin monotherapies (as monotherapies threaten the therapeutic life of ACTs by fostering the spread of resistance to artemisinin) (WHO, 2010). The government then undertook aggressive actions to enforce the ban through medicines regulatory measures and activities. Efforts to strengthen regulatory capacity and enforcement (including QA of antimalarial medicines and combating counterfeit medicines) included training for police to identify and investigate counterfeit anti-malarials and enforce ban on oral artemisinin monotherapies and improved collaboration between medicines regulatory authorities, police and customs. On February 9, 2011 Cambodia signed the Cotonou Declaration against falsified medicines, a week before inaugurating the Central Office for the Fight against Trafficking in Counterfeit Goods, which brings together civil and military police, customs officers, and health inspectors in Phnom Penh. In April 2011 the French Ministry of Foreign Affairs established the Priority Solidarity Fund Project to support the national authorities of Lao PDR, Cambodia, Thailand, and Viet Nam in the fight against counterfeit products in the GMS. In Myanmar, the Food and Medicine Administration has stopped issuing registration certificates for new oral ART monotherapies and will not renew the validity of those that become expired. The FDA medicines quality monitoring and post-marketing inspection and regulatory actions will be strengthened.

Public awareness raising about the dangers and issues of SCMs in the GMS has been one of the activities led by the Promoting the Quality of Medicines (PQM) program to promote both public awareness and advocacy to engage policymakers through regionally-produced documentary films, televised public service announcements (PSAs), posters and leaflets, radio spots, and other IEC materials.

Regional initiatives to address counterfeit medicines have included the establishment of a strategy by USP PQM (a successor of USP DQI) to Build Regional Expertise in Medicines Regulation and Enforcement (BREMERE) which prioritizes the development of training modules for medicine registration, the development of local expertise in medicine regulation, the sharing of technical resources and expertise in problem-solving and the promotion of south-south cooperation. The development of an Online Medicines Quality Database was officially launched in April 2011 which lists authenticity testing results for 8,700 medicine samples to date, including key anti-malarials medications obtained from street vendors, pharmacies, stores and clinics worldwide. The database is freely accessible online, and contains critical quality data such as the time and location of medicine sampling. A key feature of the database is that it identifies the location of where counterfeit medicines are being manufactured, allowing countries to identify which medicines are being counterfeited in neighboring countries and increasing awareness of products of concern (http://www.usp.org/app/worldwide/medQualityDatabase/terms.html). In the GMS, results of surveys conducted by various partners coordinated by national programs, such as ACTWatch, have shown that fewer counterfeit and substandard antimalarials were marketed in 2010 than in previous years, indicating some measure of success (ACTwatch, 2009; Delacollette, 2011).

As a result of efforts made by the Roll Back Malaria Initiative partners and the WHO, and United States Pharmacopeia in particular, most funding proposals for malaria control supported by the Global Fund To Fight AIDS, Tuberculosis and Malaria now include a strategic component to monitor counterfeits and substandard medicines (Delacollette, 2011).
Governments have received extra technical and financial support for regulation and law enforcement, including capacity building to monitor imports and the distribution of medicines, vaccines and laboratory reagents.

Despite advances, problems continue to persist in the form of sporadic availability of poor-quality pharmaceuticals, either manufactured in-country or imported illegally. In addition, GMS countries suffer greatly from the following key constraints:

- Human resources: National experts and civil servants remain inadequately trained in the quality assurance and quality control (QA/QC) of medicines, many of whom are over-extended with multiple responsibilities but low salaries.

- Limited institutional capacity: Implementation of rules and regulations regarding pharmaceuticals is complicated by the non-alignment of regulations from multiple institutions. For example, customs agents examine whether or not a pharmacy complies with financial requirements (eg, paying taxes), while the Ministry of Health examines qualifications of the staff operating the pharmaceutical establishments.

- Poor coordination among in-country law enforcement agencies: Ineffective mechanisms for sharing information on SCMs in a timely manner results in limited concerted enforcement action.

- Weak inter-country and regional cooperation: Cooperation, collaboration, and coordination of information-sharing, collective investigation, and enforcement on SCMs found in the region remains weak and limited.

- Continuing limited public awareness about SCMs: Neither regional public education campaigns nor an effective rapid alert system has been put in place in the GMS.

Thus, further strengthening of institutional capability and collective enforcement of legislation and regulation are of paramount importance.

Recently WHO and ASEAN groups on communicable diseases and pharmaceutical development have joint effort to boost action to address above-mentioned issues. A meeting was organized in Bangkok on April 24-26, 2012 with concrete action points to be further endorsed by high level decision-makers (WHO, 2012).

*Middle-East*

According to WHO figures, counterfeits account for as much as 35% of the pharmaceutical market in the region. Available data suggests that Viagra, antibiotics, psychotropic medicines, and oncology heart and liver medicines are most commonly counterfeited.

Disturbingly, counterfeit medicines appear to have penetrated both the informal and formal sectors in Western Asia. Free trade zones - specially designated areas with no tariffs and minimal regulatory oversight to encourage trade - undermine the safety of supply chains and encourage illicit activity. In 2012, EU customs officials reported that a third of the medicines they confiscated along its borders originated from the UAE, which has several free trade zones.

Other factors, which contribute to the prevalence of counterfeits, include a lack of appropriate legislation, weak regulatory authorities, poor enforcement, corruption, and the sheer sophistication of the illegal medicine manufacturing industry.
Some great ports of the Middle East are being used as illegal trade hubs serving the global commerce in such products worth perhaps $30 billion a year, according to World Bank estimates. In this context, Dubai is particularly attractive to counterfeiters because of its strategic position. Located in the Persian Gulf, Dubai lies on a major trading route, which connects Asia, Europe and Africa by both land and sea. Nearly a third of all counterfeit medicines confiscated in Europe in 2012 passed through the UAE.

The illegal trade in counterfeit and substandard medicines enriching a wide range of traders and manufacturers as well as terrorist organizations has thoroughly infiltrated most pharmaceutical markets of the Middle East, according to an authoritative new study published in Washington. The counterfeits look like proper pharmaceuticals, but their expensive, life-saving active ingredients are missing - replaced by cheap, ineffective and sometimes even lethal alternatives.

Such adulterated products disseminated across the Middle East, including essential heart and cancer medications and antibiotics, undermine the usefulness and reliability of all medical services there. Worldwide, the number of lives claimed by counterfeits is counted in hundreds of thousands.

Syria, Lebanon and Egypt have emerged as the regional focal points of this criminal enterprise, with tentacles extending to Iraq, Iran and Turkey.

A report published by the American Enterprise Institute - The Deadly World of Falsified and Substandard Medicines - observes that the proliferation of fake medicines has deprived the Syrian insurgents seeking to topple the regime of Bashar Assad of the means to treat their battlefield wounded.

Syria two-year old war civil war has so far cost more than 70,000 lives, according to UN estimates. The UN's World Health Organization (WHO) fears the deteriorating medical services may spawn major disease outbreaks. This was a contributing factor to a decision just announced by the United States and its European allies to provide medical, administrative and other non-lethal assistance to the insurgents.

Most of the counterfeit and frequently contaminated medicines consumed in the Middle East originate from India and China. But Assad's ally Hizbullah, the Lebanon - based organization implicated in major terrorist murder investigations in Europe and the Americas, has become a substantial source of fakes, according to recently released court documents. Its source of smuggling on sale in the Middle East, Eastern Europe and elsewhere is believed to be a hub of medicine laboratories operating in the Beqaa Valley.

A strategic component of the drive to rid the world of counterfeit medicines was initiated at a recent regional conference in Dubai. It heard that some 9% of all imported pharmaceutical fakes seized in the European Union had passed through the UAE.

The UAE health ministry has since then tightened up the supervisory regime enforced at the country's transshipment ports as well as the free-trade areas. But it is clear that no administration alone is likely to succeed in arresting this insidious international commerce until the major trading nations manage to evolve a joint strategy.

Other countries are concerned. Israel for example, is very vigilant. Already in 2007, according to the Manufacturers Association of Israel (MAI), sales of out-of-date, counterfeit, and stolen medicine for human and veterinary use reached between $28-37 million. In 2009, the Pharmaceutical Security Institute reported 52 instances of counterfeit medicines seized/discovered in Israel, making it the 9th highest ranking country in the world.
That same year, the Israeli Health Ministry estimated that more than 50% of prescription medications advertised in Israel's print media are counterfeit.

Cases of counterfeit medicines are widely reported in Israel, and commonly involve anti-impotence medicines and general antibiotics. In 2007, the Israeli Customs Authority seized a shipment of counterfeit medicines from a container ship from China which included 11,820 fake Viagra pills, 800 fake Cialis pills, and several hundred other unidentified pills. A 2008 raid led to the seizure of a leukemia treatment that contained no active ingredients.

That same year, inspectors from the Israeli police and Health Ministry found 6,000 suspected counterfeits pills in Tel Aviv, Haifa, and Jerusalem, including anti-impotence medicines, anti-narcolepsy medicines, contraceptives, antibiotics, and psychotropic medicines. The following year, the Health Ministry shut down Neve Avivim Pharmacy in Ramat Aviv, which was selling counterfeit and unregistered medicines. In December 2009, the Tel Aviv Public Prosecution successfully tried a ring of counterfeiters, who had been distributing anti-impotence pills through the Internet, under the Criminal Code. Two of the defendants were sentenced to 16 months in prison and fined $14,000.

In order to stem the rising tide of counterfeit imports, the Health Ministry established the Pharmaceutical Crime Unit (PCU) in 2007. As of November 2009, it only had three employees—a lab technician, a former head of police, and an inspector with a Ph.D. in Pharmacy. Despite its small staff, the PCU has uncovered multiple smuggling rings. It has confiscated counterfeit Tamiflu, exposed an illegal trading ring selling Ritalin which causes non-ADHD patients to get "high," and intercepted ping-pongs balls containing the raw material used for producing Viagra at Ben-Gurion airport.

V. Public Health impact

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 counterfeit medicines for the treatment of life-threatening conditions such as malaria, tuberculosis and HIV and AIDS.

Two types of counterfeits especially attract our attention: overdosed and under-dosed products.
Overdosed product

An individual may overdose accidentally, taking the wrong quantity, combination or type of medicine, unaware that it poses health risks. Taking legal medicines in quantities or combinations other than those recommended can result in an overdose. Illegal medicines (including counterfeits) and natural remedies are often manufactured in unregulated environments, meaning that the type, quality or quantity of active ingredients is unknown and the safety and efficacy of the products have not been tested. There is also potential for accidental overdose from these medicines.

The effects of medicines on the vital organs that they target partly depend on the means of administration. Overdosing can alter these organs and put the patient’s life at risk.

The first organ to be affected by overdoses in the event of oral ingestion is the stomach. For example, anti-inflammatory medicines can cause gastritis and even stomach ulcers. Moreover, when using these products, it is always advisable to take a gastric demulsant to prevent “illnesses” caused by incorrect use.

The liver is the second organ affected due to its role in detoxifying the body. If the doses absorbed are too high they can exceed the liver’s detoxification capacity and destroy the organ’s cells and cause liver failure.

Overdoses also affect the blood, which transports medicinal substances in its different constituents: red blood cells, white blood cells and platelets. When an overdose occurs, their capacity is exceeded, making them unable to transport the medicine and diminishing or making them totally unable to carry out their primary role, which can lead to anaemia, granulopenia or thrombopenia, which are serious illnesses aggravating the overdosing effects.

The kidneys are the fourth organs affected since their role is to purge the body of substances dissolved in the blood. An overdose will limit the kidneys’ capacity to purge and they will be unable to eliminate excessively high toxic doses totally. Furthermore, the level of nephrotoxicity of certain products can cause kidney failure.

In the body, medicines are transported towards the target organ to be stored there and to act on it.

The central nervous system is affected by risks of encephalopathy and neurological disorders, which are not always reversible. This can affect certain nerves, such as the acoustic nerve, which can cause deafness, the optic nerve causing blindness, and peripheral nerves, which can lead to polyneuropathy.

Overdosing can therefore affect all vital functions, resulting in death due to the body’s incapacity to process the medicine.

Thus for example, alternative Chinese medicine product found on the market in Singapore, “Tung Shueh Wan”, contained four undeclared ingredients - caffeine, diazepam, indometacin and prednisolone - whose potential adverse effects are depression, bone loss, spontaneous fractures, gastro-intestinal bleeding or even coma.
**Under-dosed product**

Attention must also be paid to under-dosed medicines. Insufficient doses of active ingredients can cause therapeutic failures, extend the period of infectiousness, aggravate the illness and increase the cost of treatments and therefore make patients less likely to comply with prescriptions. Moreover, in the case of antibiotics, it considerably increases the risk of developing resistance, which not only has repercussions on the individual, but also on the population in general. Finally, under-dosage can also result in a form of mithridatism, where the body gets used to small repeated doses; this is not only true in humans but also in the bacteria and viruses, which may also become resistant through mutations.

This is the case of antibiotics and antimalarials, which are often misused and thereby rendered ineffective.

With regard to antibiotics, there are many examples of resistance to bacteria, such as golden staph (Staphylococcus aureus), which can no longer be treated with antibiotics due to the resistance that it has developed.

Resistance to antimicrobials, including antibiotics, is one of the most alarming current health problems. Are we really in danger of becoming unprotected for lack of effective medicines? And by allowing an increase in the sale of under-dosed counterfeit antibiotics, are we also in danger of being unable to treat infections?

In 2011, the WHO chose to focus on anti-microbial resistance (or medicine resistance), as a major, and rapidly growing, health issue.

Although the purpose of anti-microbials is to fight infections (bacterial, viral, fungal or parasitic), the last few years have seen a decrease in their effectiveness on microorganisms, which used to be known for being sensitive to them. The result is that it is becoming increasingly difficult to treat patients, who therefore suffer from the illness for longer and run a greater risk of death for lack of solutions.

**High medicine resistance death toll**

The treatment of malaria has thus become more problematic, but it is mainly the resistance to antibiotics that is of concern. Every year, 150,000 deaths are attributed to cases of multi-resistant tuberculosis, which affects some 440,000 people every year. Hospital-acquired golden staph infections have also increased.

This resistance comes from the misuse of antibiotics or from the repeated use of under-dosed antibiotics, which leads microbes to acquire mutations becoming “super-bacteria”, “super-resistant” or even “multi-resistant” bacteria (superlatives indicative of concern in the medical world).

There has recently been much talk of NDM-1 bacteria, or of the bacteria discovered in a hospital in Marseille, France. There is, therefore, a non-negligible risk of finding ourselves confronted with the same situation that our ancestors experienced (before the discovery of antibiotics at the beginning of the 20th century), where epidemics could ravage entire population without any means of stopping them.

In the case of malaria, its protozoan can become resistant to antimalarial medicines to such an extent that two zones have grown up in endemic countries:
• non chloroquine-resistant countries. Here chloroquine or nivaquine is still a curative medicine;
• chloroquine-resistant countries where, to be effective, the medicines used combine chloroquine and proguanil, but at small doses that comply with legal manufacture.

It is advisable and even recommended to avoid using medicines circulating in those countries as under-dosed- and therefore dangerous- counterfeits are distributed in large quantities and contribute to resistance to existing medicines.

*Of course, other types of medicines must also be taken into account.*

The complete absence of active ingredients evidently increases morbidity and mortality due to disease through therapeutic ineffectiveness. A few years ago, the French organization *Pharmaciens Sans Frontières* discovered that fake ampicillin, only containing flour, was being sold in markets in Haiti. In 2000, the Columbian pharmaceutical authorities confiscated 6 million doses of Voltaren® (diclofenac), which only contained coloured water.

The abovementioned composition problems also include:

• In the case of medicines whose active ingredient differs from the ingredient indicated on the labelling, the consequences include therapeutic ineffectiveness, the possibility of interactions and adverse effects as well as the increased probability of overdoses. If we take the example of a counterfeit of the antiretroviral Combivir® (lamivudine, zidovudine) where the pills had been replaced with those of another product, Ziagen® (abacavir), the danger mainly lay in the possibility of abacavir overdoses (given the different dosage recommendations for these two products), and in potentially mortal hypersensitivity reactions (2 to 5% of cases where abacavir is found).

• When a medicine is intentionally made up of toxic ingredients alone, its ineffectiveness is combined with the danger of possible intoxications.

• Medicines that include active ingredients in addition to those indicated on the label are particularly dangerous. They increase the risk of medical interactions and overdosing, risks of allergies and the development of other adverse effects of varying intensity.

But these also include problems linked to microbiological and chemical contaminants:

• Certain medicines that do not comply with good manufacturing practices can suffer from microbial contamination. This increases the risk of infection considerably, especially in immunodepressed or vulnerable patients, or if the medicine is administered invasively (intravenous, intramuscular, intraocular administration, etc.). For example, counterfeit Procrit® (epoetin alfa) - a medicine used for cancer research and HIV patients - on sale in the United States, was found to contain only non-sterilized water, which could have caused serious infections, such as septicaemia.

• Chemical contaminants can be particularly harmful. In certain concentrations, patients run the risk of suffering acute, chronic and sometimes mortal intoxications. The impurities produced by the active ingredient (related substances), by the excipients or by the manufacture of the final pharmaceutical product (residual solvents, catalysts) must be kept below the concentrations established by the regulations. However, these limits are regularly exceeded: traditional alternative medicine products are often contaminated with heavy metals like lead, cadmium, mercury or arsenic. These metals are often found in very strong concentrations, causing blood poisoning, peripheral nerve damage, brain damage and many other obnoxious effects in patients. In addition,
diethylene glycol intoxication epidemics have occurred in many countries such as India, Nigeria and Haiti. Patients had taken medicines contaminated with this substance and had rapidly showed signs of severe kidney failure. Many of them died. The incidents referred to above were not attributed to counterfeits (there is often no evidence). Although some medicines were strongly suspected, the criminal nature of the violation of certain quality assurance procedures is often difficult to assess.

Or stability problems:

Products that have not undergone correct stability tests or where the use-by-date has lapsed, but have been fraudulently relabelled in order to extend their shelf life, pose two dangers. The first concerns the possible appearance of highly-toxic degradation products, such as tetracyclines (the epimerization of tetracycline is responsible for renal tubular damage of the Toni-Debré-Fanconi type). The second danger is the possible decline in the therapeutic effectiveness of the medicine, a particularly high risk when the therapeutic margin is narrow (antineoplastics, theophylline, digoxin, etc.).

Another problem in developing countries is poor access to active ingredients, which is often the cause of therapeutic failure. Low availability is often the result of a poorly controlled manufacturing process or a change in the nature of the excipients.

During a conference, GlaxoSmithKline revealed that their medicine Imuran® (azathioprine) had been counterfeited and that, although the seized product contained the right amount of active ingredient, it did not comply with rules on disaggregation. After 4 hours in water, pills remained intact, when they should have dissolved after 45 minutes.

Lastly, problems also concern interaction with the recipients:

The manufacturer must ensure that there is no interaction between the contents and the container. There are two types of possible interactions:

- migration and fixation of the contents on the plastic material via absorption mechanisms, thus modifying the stability of the product and its concentration, causing potentially toxic effects and/or lower effectiveness,

- release of the constituents of the container into the contents, thus modifying the stability of the pharmaceutical preparation and potentially causing intolerance or toxic phenomena.

Case study in the Democratic Republic of Congo

In Uvira, South-Kivu, a province of the Democratic Republic of Congo, a large number of malaria or typhoid fever patients fail to recover despite following the treatments prescribed. They are victims of ineffective counterfeit medicines, which are hard to detect. Only certain medical centres select their suppliers and pharmaceutical products carefully.

Last April (2011) the local order of pharmacists signalled that, on analysis, a box claiming to contain 500 mg of quinine, turned out to contain compact manioc flour with no active ingredient.

In March 2011, the South-Kivu provincial health minister had already warned the local population of the circulation of fake medicines, especially erythromycin, an antibiotic. In Uvira, 70 to 80% of patients brought in for consultations suffer from malaria or typhoid fever. Some, after having taken tablets, relapse and their condition worsens, requiring treatment via drip, the last resort. Medicines in the form of tablets failed to have the effects that the medical personnel
expected, even when complying with the dosage. A doctor directing a local medical course explains that this is a case of counterfeiting " For some time now, I have request that patients buy their medicines at my office desk." Some medical centres, like the general referral hospital in Uvira and the Hospital Centre of the 8th CEPAC/Kasenga, also do this. Others, who are not as rigorous in choosing their suppliers, are at the mercy of pharmaceutical counterfeiters. Various smaller establishments do not have permanent supply sources, despite the existence of a central pharmacy in the health district. Their patients experience passing relief linked to the antipyretics/pain-killers (paracetamol, aspirin, etc.) often associated to the treatment of these two diseases. However, as soon as they stop taking these medicines, the symptoms reappear as if no treatment had been administered.

Concerned families move patients from one medical centre to another. Those who cannot afford to continue, buy counterfeit medicines cheaply resulting in highly dangerous conditions requiring the patient’s hospitalization. Such cases are common in pregnant women and children under five.

A nurse working in the private hospital of Kimanga, one of the fourteen districts in the city of Uvira, recommends, when buying medicines at local public pharmaceutical sale points, to check the colour and size of tablets before paying. Counterfeiting generally targets expensive medicines such as quinine and ciprofloxacin to treat typhoid fever. According to local doctors, counterfeiting occurs at different levels: in the packaging, the labelling, the substitution of one product for another, and especially the absence of active ingredients in these medicines, making them ineffective. The problem is that imported medicines are never analysed. Since the Congolese Control Office (OCC) was established in Uvira, no laboratory has been set up. After tax, the goods are released without further analysis. Many medicines thus enter the country without having been controlled. Even in Bakavu, despite the existence of a laboratory, analyses to determine the presence of active ingredients are not guaranteed.

VI. Health: a key area for organized crime

We know from past experience that in times of crisis, health outcomes and the risk of health-related financial hardship may be affected by changes in the resources available for health systems (financial and human resources, medicines and medical devices, running costs and infrastructure), by changes in living conditions, lifestyles and consumer behaviours, and by changes in social norms and values. Ideally the health system can and should do three things: protect those most in need, concentrate on areas in which it is effective and adds value, and behave as an intelligent economic actor in terms of investment, expenditure and employment.

In countries whose health system is financed through general tax revenues, decreases in GDP and economic outputs have resulted in significant reductions in public revenue for health. Alternatively, in countries that rely predominantly on wage-related contributions to health insurance funds, increases in unemployment have constrained revenues earmarked for health. International prices for medicines and other consumables have increase owing to inflation and currency depreciation. These pressures on revenue generation and purchasing power persuade policy-makers to cut budgets, introduce or increase user fees, co-payments or other forms of private financing, reduce benefit packages or tolerate longer waiting times.

However, although both detailed and synthetic economic reviews and forecasts have been published at least quarterly since mid 2009, the direct effects of this multidimensional crisis on health are still unclear.
So far, the information and evidence available on the precise impact on individuals, vulnerable groups and the health system in general remain anecdotal and fragmented. Furthermore, this type of data is proving difficult to compile and analyse; existing health information and monitoring systems are proving rather unfit to serve the needs of policymakers regarding these critical issues in many countries.

Few changes in health system expenditures have been observed. The European health sector (which employs about 10% of the total workforce) seems not to have lost many jobs and in fact appears as a stabilizing sector. As is also the case in the United States, health is indeed one of the very few economic sectors that is still creating jobs. The “credit crunch” seems to have mostly affected health-related private investors or medical insurance schemes and undermined some forms of public/private partnerships. Depreciations have increased the prices of imported medicines and medical devices in the countries concerned, causing initial problems to the less rich among the affected countries. Already facing threats in terms of expiry of patents on “blockbuster medicines” and rising research and development costs, the pharmaceutical industry has signalled difficulties in accessing credit and seems to expect additional downward pressures on medicine prices.

Whether or not it is related to unemployment, the foreseeable reduction in household income affects private expenditures on health and the ability of families to pay for health care. It is known that globally 150 million people are pushed into poverty yearly through the catastrophic household health costs that result from payments for access to health services. It is known that non-adherence to medical treatment could in the longer term result in wider prevalence of disease, complications of chronic conditions and increased medicine resistance in the case of infectious diseases.

Rising unemployment, the deterioration of millions of people’s living conditions, and the additional stress caused by the crisis have led to less healthy lifestyle choices or riskier behaviour – such as increased use of smuggled cigarettes, medicines and alcohol. It is known that even small changes in behaviour today, compounded over time, could manifest themselves in health outcomes years later. Signs of individuals changing their behaviour have been reported in ways that have a negative impact on health. For example, there have been reports of increasing consumption of fast food, and the purchase of cheap but uncontrolled food products, threatening to create new dangerous pathologies.

The IMF, the World Bank, the Organization for Economic Co-operation and Development (OECD), the European Commission (EC) and some other agencies are producing very similar economic forecasts. According to these, global growth rates could gradually recover in 2012, though only to lower levels than the ones observed in 2007 (up to 2%).

However, in the current economic climate, all experts agree that the uncertainties attached to any forecasts are very large – there are many risks, financial market conditions will take time to normalize, whatever the approach adopted, and it takes longer for industries to recruit than to fire. Not only is the outlook on the downside, but also the risks of a long and deep recession or even a depression cannot be excluded. As the crisis evolves, some issues are emerging regarding possible approaches and measures to help resolve it. Some revolve around the relative priority to be given to investment versus boosting consumption in economic recovery programmes, around how to minimize social damage and protect the most vulnerable groups, and even around what role the health sector could play as an economic area to help countries get out of the crisis. Member States are considering different approaches to perform better and doubt whether the crisis should be used as an opportunity to introduce drastic, often long-postponed changes in functions and in the overall architecture of their health systems.
The health impact of the rapid deterioration in public finances is already strongly felt. In view of the levels of public debt, it is more than likely that the fiscal “room to manoeuvre” will remain limited. The deterioration of public finances and a consequent shrinking of fiscal space could force governments to adopt drastic adjustment and austerity measures. Resources for health systems could be under severe pressure in the years ahead. Health authorities and related stakeholders will have to navigate through particularly difficult times in the foreseeable future, including focusing on what will happen after the crisis (for a start, debts will have to be paid).

The effects of the crisis on health and health systems vary significantly from country to country, depending on the structure of their economy, their dependency on exports and/or fluctuations in their domestic currency, as well as the policy actions developed by their government. There will certainly be no “one size fits all” or ready-made approach. In such a context, solutions will have to be customized to meet countries’ specific needs. Exchange of information and experience between countries and coordination of activities will certainly be needed, but supporting the preparation and implementation of country-specific programmes has to be the top priority.

Moreover, public authorities are becoming more sensitive to the crucial importance of the health sector and to the role of the health sector in the economy. Thanks to campaigns to introduce primary health care, Health for All and Health in All Policies, the work of the Commission on Social Determinants of Health and the Tallinn Charter on Health Systems for Health and Wealth, many policy-makers in the WHO European Region now recognize that making health services accessible is one of the most effective and efficient ways to reduce poverty and social inequalities, and that investing in health is good for social stability and for the economy. The experience in Finland in the crisis in the 1990s is being corroborated every day, indicating that in times of economic disaster robust health systems protect people and preclude many from having to face disease-related catastrophic expenses.

Since strong health systems are essential for weathering the storm, the commitment by Member States in the WHO European Region to strengthening their health systems based on the values and principles agreed in the Tallinn Charter is more relevant than ever (“to promote shared values of solidarity, equity and participation through health policies, resource allocation and other actions, ensuring due attention is paid to the needs of the poor and other vulnerable groups”). The particular social context will need to be carefully taken into account in determining the precise way to strive for equitable health gain, financial protection, responsiveness and efficiency improvement. Member States need to carefully review the way they provide services, generate the necessary inputs, finance their services and provide stewardship for the ensemble of all public and private organizations, institutions and resources mandated to improve, maintain or restore health within the political and institutional framework of each country.

Nevertheless, countries with a highly monitored public health system would be advised to be particularly vigilant of everything that might appear “under control”. In 2011, France underwent a healthcare crisis due to information revealed by the MEDIATOR (benfluorex) scandal, a medicine that is thought to have caused a number of deaths (between 500 and 2000 depending on the study). According to the report carried out by IGAS, the French inter-ministerial audit and evaluation office for social, health, employment and labour policies, submitted on 15 January 2011 to the French authorities, the national agency in charge of medicine marketing authorizations, the ANSM (Agence Nationale de Sécurité du Médicament, former AFSSAPS), “incomprehensibly tolerant towards MEDIATOR” according to the IGAS members, was found to be seriously wanting in its approach and in the organization of its pharmacovigilance system. Likewise, the French public authorities have been blamed for their poor monitoring of pharmaceutical networks.
This case has at least highlighted, among other things, the AFSSAPS’s lack of control, for lack of resources, over generic medicines sold in pharmacies. According to previous studies submitted to the Ministry of the Interior between 2004 and 2006, the dosage of certain generic medicines no longer meets marketing authorization requirements, once again indicating the vulnerability of renowned health systems to the risks of official and bona fide sales of potentially counterfeit medicines.

In this context and considering the threat of organized crime in the area of pharmaceutical crime, as stewards of their respective health systems, ministries of health have a duty to offer a deal to the other stakeholders and advocate for government policies that take a central position in terms of stewardship and health financing, as well as a pro-health and pro-poor approach across all sectors. This is certainly the case when it comes to discussions with ministries of finance, in the context of economic recovery plans, regarding the share of the budget to be allocated to health and other social sectors, which should not focus merely on growth or on the immediate protection of existing jobs.

In order to anticipate risks, it will be essential to make regular analyses at national and international levels of the economic and social situation and its effects on health and health systems. In many cases, the existing information systems in Member States may not be able to provide, in a timely manner, the health intelligence needed by decision-makers and other stakeholders. A WHO-supported virtual network and exchange platform and a “hot line” are being put in place at regional level, to help ministries and stakeholders access relevant information and advice. Ministries or other health-related authorities may also need to function in a “crisis management” mode, emphasizing the collection of information (including anecdotal), regularly analysing the situation, articulating strategic options and suggesting anti-crisis measures and interventions, taking the criminal threats of dangerous counterfeits and illegal trafficking of medicines into account.

With the scarce information available, it is hard to predict at this stage with any accuracy how people in Member States will be affected. However, the experience gained and lessons learned from previous crises helps to direct attention towards specific issues in order to anticipate difficulties, explore options and prepare anti-crisis measures.

**Chinese triads: an example of transnational crime**

Today, the triads are key players both in Asia’s informal economy and in all other major continents. These groups can be compared to the Italian mafia. They are involved in racketing, prostitution or the counterfeit trade. They are becoming increasingly specialized in human trafficking, which is one of the most profitable branches of criminal activity.

Poor segments of the Chinese population seeking to improve their lot, give themselves up to smuggling networks controlled by the triads. They pay considerable sums and often work for long periods in underground workshops set up in host countries. This is a modern form of slavery that has been associated, for a number of years, to the manufacture and assembly of counterfeit products in market areas. The triads are also behind the trafficking of medicines from the Golden Triangle. This region spanning Laos, Thailand and Burma, every year produces half of the world’s opium and its derivatives, the most important of which is cocaine. All these activities are now carried out on a global scale. The triads operate through the Chinese Diaspora, which, with 60 million people, is the largest in the world. A quarter of a million of this number are triad members.
Operating mostly from Asia, the triads have contacts in North America and Europe. The members, established in "Chinatowns", become the local links for these activities as part of the Tongs. These public organizations are mutual aid communities that welcome new arrivals and help them settle in. Some of them serve as a cover for money laundering centres.

With the exception of one triad, they are all established on the fringes of the People's Republic of China, mainly in Hong Kong. The handover of Hong Kong to China in 1997 caused concern among certain triad leaders. However, the communist authorities quickly calmed these fears. The Chinese government shows a strange level of indulgence towards the triads.

In reality, it was quick on the uptake as to the benefits to be had. These extremely wealthy groups reinvest a large part of their laundered capital back into China. Thus in 1995, Tao Si, then Chinese Minister of Public Security, declared "triad members are not all gangsters. If they are good patriots, if they ensure the prosperity of Hong Kong, we must respect them". He even declared that the "Chinese government is glad to be able to unite itself with them". The arrests of various triad members in 2004 did little to cover up the close ties that have developed between the Chinese authorities and these secret societies.

China is currently one of the most important counterfeit producers in the world. Traditionally known for its illegal production of luxury goods, various Chinese regions are seeing the mass industrialization of counterfeit medicines. In addition to the economic damage, these practices constitute a real threat to the health and safety of populations, both in China and in export countries. For a number of years, the Chinese government has adopted anti-counterfeiting measures to counter criticism from countries affected by it, but also because it has realized the threat that counterfeiting poses to its own economy. According to an article published in 2004 in the French magazine l'Expansion, "China is one of the primary victims of counterfeiting... 97% of disputes are Sino-Chinese", as reported by a European diplomat, specialized in intellectual property, and quoted by AFP. These Chinese statistics indicate that counterfeiting affecting foreign companies represents less than 10.5% of the cases discovered. Counterfeiting does not only affect foreign luxury brands, but also well-known Chinese brands and medicines.

From 21 to 24 May 2008, the Public Security teams of a city in the South of China, directly monitored and assisted by a high-ranking official of the Ministry of Public Security of Beijing, mobilized more than a hundred police officers in an operation to dismantle a criminal network. After various weeks of painstaking investigation, phone tapping and infiltrating the network, simultaneous raids were organized on seven different factories. 74 people (referred to as "persons in charge") were arrested and placed under police custody, 9 were remanded and placed in custody, and 2 underwent court investigation. All the medicine factories were closed down and placed under permanent police surveillance. Thousands of pieces of documentary evidence were seized, catalogued and filed. The matter was referred to the authorities in Hong Kong, from where some of the network leaders came, and they collaborated with their continental counterparts. At the end of May, the case was transferred to the Procuratorate to be referred to the criminal court competent to hear, among others, various citizens of the former British colony. The Procuratorate as "major and important" qualified the case, raised to a status of "national priority" by the Public Security.

China is becoming aware of the modern phenomenon of counterfeiting; its penal code defines it and penalizes it; its judicial personnel are tackling it.
Counterfeiting: a trade war for the pharmaceutical industry?

The dangers of counterfeiting go beyond public health concerns. Intellectual property and market protection lie at the heart of the debate. In recent years, the international division of work between countries has changed. While large emerging countries like China, India or Brazil increase their production capacity for consumer goods, the economies of industrialized countries increasingly rely on knowledge and innovation, which are materialized in the form of intellectual property rights (in particular with patents). This explains why pharmaceutical companies want to strengthen their intellectual property protection. The health risks posed by counterfeit medicines, especially in poor countries, are therefore often used to defend the interests of large pharmaceutical companies. Information divulged on the risks of counterfeit medicines abound. Reference is often made to the notion of "pharmaceutical crime" - and justly so-, a dramatic term that blurs the lines between counterfeits that pose a health risk and other forms that only have economic consequences in terms of intellectual property. This deliberate failure to distinguish between two kinds of infringement (counterfeiting in terms of intellectual property rights and counterfeiting-crime in criminal law) creates additional confusion in the already-fuzzy messages given out by intellectual property rights defence associations. Likewise, there is a regrettable omnipresence of pharmaceutical industry representatives in bodies, which should in theory be independent, as is the case in the PC-S-CP Group of Specialists responsible handling the draft criminal law on counterfeiting-crime in the Council of Europe.

Pharmaceutical companies that hold the rights for brand-name medicines are increasingly have to compete with the generics industry, especially when their brand-names (patents) expire. In this context, companies encourage the confusion between counterfeit and generic medicines. Thus, in a section on its website that deals with counterfeiting, Pfizer gives patients the following advice: “Consult your doctor or pharmacist and join a patients association (...) and seek advice from them on (...) the effects of switching to generic or different formulations, and your rights to refuse any medicine you are not confident in or are confused about. Ask about your rights to buy your standard, long-term medicine packaging.” On its German site, in its section on counterfeiting, MSD publishes a warning advising vigilance and using the phrase “Safety can only be ensured by good-quality and original medicines”. However, in industrialized countries, generics are supposed to be controlled using the same pharmaceutical quality procedures as brand-name medicines. Confusion is also created with copies of medicines that are still covered by a patent, but that are produced in developing or emerging countries that use legal patent law dispensations (obligatory licenses), as in the case of India.

Controversy over the WHO definition of pharmaceutical counterfeiting, and the difficulties of its IMPACT task force to introduce a definition that focuses on “Public Health” instead of “Intellectual Property Protection”, is an indication of the influence being exerted by the brand-name pharmaceutical industry to refocus the debate on industrial protectionism.

Globally, the highly controversial discussion of the Anti-Counter Trade Agreement (ACTA), was launched in 2008, and continued into 2009\(^1\). This treaty, steered by the US trade representative, the European Commission, Japan and Switzerland, proposes to abolish the distinction between piracy (or counterfeiting) and all intellectual property violation through patent infringement.

\(^1\) Discussions in view of an anti-counterfeiting and piracy agreement, launched in June 2008, continued in Paris from 15 to 18 December 2008, under the European Union presidency. As for all the preceding cycles, delegations from Australia, Canada, Korea, the United States, Japan, Morrocco, Mexico, New Zealand, Singapore, Switzerland and the EU (European Commission and French presidency) participated in the negotiations. Representatives from EU Member States were also present. The last round of negotiations was held in Rabat, Morocco, from 16 to 17 July 2009.
This measure would make patent infringement liable not only to civil but also to criminal sanctions, where such infringement could be interpreted as a “crime relating to counterfeiting activities”. International agreements on patents (in particular “obligatory licenses”) however give governments the option of not recognizing patents (subject to certain conditions). Confusion at an international level filters down to the national level; in 2008 Kenya drew up a draft anti-counterfeiting law which defines “pharmaceutical counterfeiting” in such vague terms that all generics could be considered to be counterfeits. Such provisions could jeopardize access to generic antiretrovirals for Kenyan HIV-positive patients.

The solutions put forward by the WHO IMPACT task force focus on 5 major areas:

- Reinforcing legislative and regulatory protection measures against counterfeiting, particularly by increasing sanctions;
- Protecting distribution circuits in countries where control structures are weak, by guiding and counselling national health authorities;
- Coordinating investigations on a global level to identify the sources of counterfeit medicines and arrest counterfeiters;
- Developing technical mechanisms to improve the traceability of products;
- Providing the public with more information on the risks of counterfeit products in general.

This state of play requires prioritization. Pharmaceutical counterfeiting is an illegal and unjustifiable activity, which can have dramatic consequences on health, especially in the poorest countries. It was hard to measure the true extent of pharmaceutical counterfeiting. A rational approach to this problem requires reliable figures obtained through independent market surveillance studies, and the establishment of provisions obliging manufacturers to declare counterfeiting cases to Health authorities. The media has given an imbalanced portrayal of the phenomenon of counterfeiting, which does not take into account the root causes of the existence of a counterfeit medicine markets, which are the disarray of pharmaceutical circuits, corruption and poverty among patients. The priority is not to protect the market through sophisticated legal measures. It would be better, especially in poorer countries, to strengthen pharmaceutical circuits (especially importations, local industries, packaging for sale in retail outlets and sale points), improve control over them through operational State anti-counterfeiting technical centres (in collaboration with NGOs), strengthen the principle of counterfeiting-crime and enhance the reliability of technical evidence, improve patients’ access to good quality healthcare, raise public awareness with the assistance of NGOs and take determined action against the production of substandard medicines and fraud, which, although less publicized, are more widespread that counterfeiting itself.

*Corruption: a determining factor in the distribution of fake medicines*

As seen in preceding chapters, pharmaceutical counterfeiting results in thousands of deaths throughout the world, but particularly in poorer countries. A study by the German NGO Transparency International, published in London in 2008, indicated the dramatic global increase in pharmaceutical counterfeiting over the last five years. This study also confirms the danger of these counterfeits in particularly corrupt medical environments. Embezzlement, bribes and extortion deprive thousands of people of adequate healthcare.
For a large majority of developing countries, although most health sector employees carry out their work diligently and honestly, there is nevertheless strong evidence of fraud and corruption throughout the healthcare system: from minor instances of theft and extortion to major distortions of healthcare policies through embezzlement in the form of bonuses for civil servants. Corruption affects all the links in the chain of healthcare services, in both the private and public sectors, and affects all types of services, from the simplest to the most complex:

- Hospitals in the Central African Republic have become a cash cow for certain people, using non-transparent distribution, procurement and supply systems.
- Health sector employees demand payment for services that should be free. In Bulgaria, as in most South-Eastern European countries, doctors often accept small informal payments or presents in exchange for their services. These sums vary and can go from 10 to 50 US dollars and, in certain cases, can go up to 1100 US dollars.
- In the Philippines, there is evidence that a 10% increase in fraud and extortions by healthcare personnel had led to a 20% reduction in child vaccination rate.
- In Cambodia, certain health indicators have declined, partly due to the direct embezzlement of funds earmarked for public health, despite the increase in foreign aid to the health budget. However, since 1999, strengthened control mechanisms in the United Kingdom have reduced losses due to corruption in the Cambodian health system by almost 300 million US dollars.
- In Costa Rica, nearly 20% of an international credit of 40 million US dollars intended for healthcare equipment disappeared into private coffers. “Corruption erodes citizens’ confidence in the medical system. Patients have the right to demand that the medicines are not counterfeits. They also have a right to expect doctors to give priority to the patient’s interests over their own profit making. And above all, they have the right to believe that the ultimate aim of a health system is to heal rather than kill”, declared David Nussbaum, the Director General of Transparency International.

For millions of poor people at are still at the mercy of unscrupulous health-care providers, the eradication of corruption in the health sector is a matter of life or death. “The cost of corruption in the health sector goes far beyond financial losses. How can one put a price on the death of a child that dies during an operation because an injection that should wake him up contained water instead of adrenalin?” asks Huguette Labelle, President of Transparency International. “The price of corruption in the health sector is human suffering”.

In this context, the progress of illicit trafficking does not come as a surprise. Aggressive marketing techniques drive doctors to give undue preference to certain medicines, increasing prescriptions that are not always based on the real needs of patients. The annual turnover of the pharmaceutical industry is estimated in tens of billions of US dollars for the sale of certain products. The sale figures are constantly increasing and the budgets of lobby groups largely exceed expenditure on essential research and development for the production of new medicines that could save lives in poor countries. Corruption underlies the lucrative trade of pharmaceutical counterfeiting. Illegal payments at all stages in the chain facilitate the movement of counterfeit medicines from their source to the misled consumer.

In developing countries, the purchase of medicines represents between 50 and 90% of extraordinary household spending. Corruption in the pharmaceutical industry therefore has a direct effect on populations that struggle to survive, especially since these are strongly affected by cyclical diseases (HIV, Malaria, etc.).
In the case of HIV, corruption hinders the efforts made by the international community to put an end to this pandemic. The international community’s reaction to the growing crisis caused by this disease has been to increase the financial aid allocated to it to finance prevention programmes and distribute antiretrovirals. However, if corruption is not curbed, an increase in financial aid will not alone be able to bring about the results expected. Accountability in the health sector needs to be reinforced to stop funds from being drained at all levels. The embezzlement of funds earmarked to treat disease by the ministries and national commissions for the control of the HIV pandemic deprives patients of adequate health care. For example, the Kenyan National AIDS Control Commission has become a gold mine for senior officials who have embezzled essential resources by using puppet organizations specially created to cash into these funds.

Corruption can directly contribute to the spread of this pandemic, when relatively cheap measures, such as the use of sterile syringes or tests prior to blood donations, are ignored because the corrupt practices in the procurement and distribution of products slow down supply.

Corruption also undermines progress towards the United Nations Millennium Goals, three of which are directly linked to health through the reduction of child mortality, the improvement of maternal health and combating HIV/AIDS, malaria and other diseases. "Poor families that cannot afford private healthcare, especially in rural zones, are confronted with a painful dilemma and must often chose between providing their families with food or getting health care. They have the choice between feeding their children or paying for their healthcare, but not both. No parent should have to make that choice", said Huguette Labelle.

Transparency is obviously the best way to eradicate corruption in the pharmaceutical industry and in the health sector:

- Donors and governments need to provide access to key information on projects, budgets and health policies. Information relating to budgets must be available online and be submitted to independent audits.
- Governments must adopt and apply codes of conduct for health personnel and private sector companies, and provide training on corruption.
- Likewise, rules should be applied regarding the management of conflicts of interest relating to the certification of medicines and the award of doctors' licenses.
- Health projects and policies should be submitted to independent controls both nationally and internationally and subject to detailed public examination.
- The procedure for awarding contracts for health equipment and medicines should be competitive, open, transparent and comply with the minimum standards on transparency established by Transparency International. The rules on managing conflicts of interests must be applied and companies involved in acts of corruption must be placed on a black list. Stakeholders in this sector should also agree to not pay bribes, as stipulated in the Transparency International Integrity Pact, in order to guarantee equal chances among subcontractors.
- Strict legal proceedings must be carried out to clearly manifest a zero-tolerance attitude to corruption in the health sector. To this end it is important to establish control mechanisms to ensure the protection of collaborators, corruption whistle-blowers within governments, pharmaceutical industries and biotechnology industries.
Appendix 1

Illegal pharmaceutical market: The worldwide financial estimation

The illegal medicine market includes counterfeit, expired products and those without marketing authorization from smuggling.

The present global financial estimation of the illegal medicine market has the sole purpose to measure the magnitude of the income generated by criminal networks. This study was carried out by the U.S. Based Organization WAITO Corp.. It was conducted in parallel with the TF-CIT consultations with private sector and Intergovernmental organisms.

This financial estimation was constructed from a large compilation of official figures collected by the WCO, WHO, UNODC, UNICRI, INTERPOL, EUROPOL, TAXUD, national Medicine Regulator Agencies, NGOs, local Chambers of Commerce and Associations of pharmaceutical industry. Corroborated, these data (usually in percentage terms) have been weighted, based on figures from the legal medicine market.

It seems important to note that these figures show very clearly in 2012 real endemic threats to Europe and North America.

<table>
<thead>
<tr>
<th>Country</th>
<th>Legal market 2012 (US$)</th>
<th>Estimation of Illegal market (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>North America</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States of America</td>
<td>325,280,000,000</td>
<td>340,000,000</td>
</tr>
<tr>
<td>Canada</td>
<td>22,000,000,000</td>
<td>150,000,000</td>
</tr>
<tr>
<td><strong>European Union</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Europe(^{12})</td>
<td>146,520,000,000</td>
<td>320,000,000</td>
</tr>
<tr>
<td>Belgium</td>
<td>7,570,000,000</td>
<td>52,000,000(^{13})</td>
</tr>
<tr>
<td>Netherlands</td>
<td>8,270,000,000</td>
<td>127,500,000(^{14})</td>
</tr>
<tr>
<td>Sweden</td>
<td>6,120,000,000</td>
<td>132,000,000</td>
</tr>
<tr>
<td>Denmark</td>
<td>3,100,000,000</td>
<td>31,000,000</td>
</tr>
<tr>
<td>Portugal</td>
<td>5,390,000,000</td>
<td>82,000,000</td>
</tr>
<tr>
<td>Greece</td>
<td>7,520,000,000</td>
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</tr>
<tr>
<td>Czech Republic</td>
<td>1,600,000,000</td>
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</tr>
<tr>
<td>Poland</td>
<td>6,000,000,000</td>
<td>40,000,000</td>
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<tr>
<td>Bulgaria</td>
<td>1,490,000,000</td>
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</tr>
<tr>
<td>Romania</td>
<td>2,600,000,000</td>
<td>318,000,000</td>
</tr>
<tr>
<td>Estonia</td>
<td>271,000,000</td>
<td>1,200,000</td>
</tr>
<tr>
<td>Slovakia</td>
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<td></td>
</tr>
<tr>
<td>Hungary</td>
<td>2,710,000,000</td>
<td>26,000,000</td>
</tr>
<tr>
<td><strong>Other countries in Pan European region</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Switzerland: 40% of illegal medicines for EU transit through Swiss borders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Russia</td>
<td>28,000,000,000</td>
<td>3,500,000,000</td>
</tr>
<tr>
<td>Ukraine</td>
<td>3,000,000,000</td>
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<td>Belarus</td>
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<td><strong>Central America</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mexico</td>
<td>15,500,000,000</td>
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</tr>
<tr>
<td>Salvador</td>
<td>?</td>
<td>70,000,000</td>
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<tr>
<td><strong>South America</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Argentina</td>
<td>5,600,000,000</td>
<td>550,000,000</td>
</tr>
</tbody>
</table>

\(^{12}\) Germany, France, Italy, Spain, United Kingdom, and Ireland

\(^{13}\) Belgium appears to be a major shipping hub for counterfeit or substandard medications coming en route from Asia to other parts of the world, particularly Africa

\(^{14}\) Netherlands is often a point of transit for fake medicines headed to other European nations. 12% of people in the Netherlands buy medicines from unauthorized channels, such as Internet pharmacies. This greatly increases the risk of purchasing substandard or counterfeit medications.
<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>22,000,000,000</td>
<td>4,400,000,000</td>
</tr>
<tr>
<td>Colombia</td>
<td>230,000,000</td>
<td>180,000,000</td>
</tr>
</tbody>
</table>

Bolivia: 40 tones of fake medicines seized. Bolivia’s Minister of Health promised to toughen up measures to combat the trade in counterfeit and substandard medicines.

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peru</td>
<td>3,600,000,000</td>
<td>700,000,000</td>
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</table>

**West Africa**

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nigeria</td>
<td>717,000,000</td>
<td>290,000,000</td>
</tr>
<tr>
<td>Ghana</td>
<td>300,000,000</td>
<td>120,000,000</td>
</tr>
<tr>
<td>Senegal</td>
<td>125,000,000</td>
<td>22,000,000</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>?</td>
<td>&gt; 10,000,000</td>
</tr>
<tr>
<td>Mali</td>
<td>135,000,000</td>
<td>41,000,000</td>
</tr>
<tr>
<td>Côte d’Ivoire</td>
<td>347,000,000</td>
<td>70,000,000</td>
</tr>
<tr>
<td>Mauritania</td>
<td>37,860,000</td>
<td>12,000,000</td>
</tr>
<tr>
<td>Benin</td>
<td>200,000,000</td>
<td>67,400,000</td>
</tr>
</tbody>
</table>

Togo: The Togolese government destroyed 80 tons of counterfeit medicines seized during 2013.

**East Africa**

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethiopia</td>
<td>422,000,000</td>
<td>92,000,000</td>
</tr>
<tr>
<td>Kenya</td>
<td>577,000,000</td>
<td>125,000,000</td>
</tr>
<tr>
<td>Mauritius</td>
<td>120,000,000</td>
<td>2,500,000</td>
</tr>
</tbody>
</table>

Somalia: Counterfeit medication sales are commonplace in Somalia. This is in part because there are a lot of people running pharmacies who are not trained medical professionals and in part because there has been no medical regulation agency in Somalia for the last 20 years.

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tanzania</td>
<td>214,000,000</td>
<td>95,000,000</td>
</tr>
<tr>
<td>Uganda</td>
<td>322,000,000</td>
<td>82,000,000</td>
</tr>
<tr>
<td>Rwanda</td>
<td>70,000,000</td>
<td>19,000,000</td>
</tr>
</tbody>
</table>

**Central Africa**

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angola</td>
<td>213,000,000</td>
<td>112,000,000</td>
</tr>
<tr>
<td>Cameroon</td>
<td>260,000,000</td>
<td>120,000,000</td>
</tr>
</tbody>
</table>

DRC: Counterfeit medicines are largely uncontrolled throughout the DRC. A reliable estimation of illegal medicines is impossible. But all experts agree to consider the DRC as the largest market in counterfeit medicines in the world. Some of them believe that the fake market could reach 70% of the national market.

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gabon</td>
<td>131,000,000</td>
<td>35,000,000</td>
</tr>
</tbody>
</table>

Congo: Counterfeit and substandard products proliferate due to a combination of self-medication and poor diagnosis by unauthorized medical practitioners. 46% of medicines sold in the country are concerned.

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sudan</td>
<td>472,000,000</td>
<td>125,000,000</td>
</tr>
</tbody>
</table>

**Southern Africa**

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>196,000,000</td>
<td>51,000,000</td>
</tr>
<tr>
<td>Lesotho</td>
<td>25,000,000</td>
<td>9,000,000</td>
</tr>
<tr>
<td>Madagascar</td>
<td>71,000,000</td>
<td>15,200,000</td>
</tr>
<tr>
<td>South Africa</td>
<td>3,800,000,000</td>
<td>260,000,000</td>
</tr>
<tr>
<td>Zambia</td>
<td>207,000,000</td>
<td>31,000,000</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>180,000,000</td>
<td>38,000,000</td>
</tr>
<tr>
<td>Malawi</td>
<td>110,000,000</td>
<td>29,000,000</td>
</tr>
</tbody>
</table>

**Middle East**

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Azerbaijan</td>
<td>129,600,000</td>
<td>12,000,000</td>
</tr>
<tr>
<td>Iraq</td>
<td>950,000,000</td>
<td>&gt; 60,000,000</td>
</tr>
<tr>
<td>Israel</td>
<td>1,600,000,000</td>
<td>30,000,000</td>
</tr>
<tr>
<td>Jordan</td>
<td>650,000,000</td>
<td>20,000,000</td>
</tr>
<tr>
<td>Lebanon</td>
<td>300,000,000</td>
<td>60,000,000</td>
</tr>
</tbody>
</table>

United Arab Emirates: 31% of illegal medicines imported into the European Union Originated from UAE.

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saudi Arabia</td>
<td>2,800,000,000</td>
<td>250,000,000</td>
</tr>
</tbody>
</table>

**North Africa**

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Egypt</td>
<td>3,070,000,000</td>
<td>300,000,000</td>
</tr>
<tr>
<td>Algeria</td>
<td>3,190,000,000</td>
<td>152,000,000</td>
</tr>
</tbody>
</table>

Libya: 80 percent of Viagra sold in Libyan pharmacies were counterfeit.

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morocco</td>
<td>1,250,000,000</td>
<td>110,000,000</td>
</tr>
</tbody>
</table>

**Eastern Asia**

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>102,720,000,000</td>
<td>900,000,000</td>
</tr>
</tbody>
</table>

15 Including smuggling
<table>
<thead>
<tr>
<th>Country</th>
<th>Counterfeit Markers</th>
<th>Counterfeited Trademarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Republic of Korea</td>
<td>20,000,000,000</td>
<td>1,500,000,000</td>
</tr>
<tr>
<td>China</td>
<td>50,000,000,000</td>
<td>4,000,000,000</td>
</tr>
<tr>
<td>Taiwan</td>
<td>3,900,000,000</td>
<td>300,000,000</td>
</tr>
<tr>
<td>South-Central Asia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kazakhstan</td>
<td>1,650,000,000</td>
<td>620,000,000</td>
</tr>
<tr>
<td>Uzbekistan</td>
<td>563,000,000</td>
<td>235,000,000</td>
</tr>
<tr>
<td>Afghanistan</td>
<td>400,000,000</td>
<td>160,000,000</td>
</tr>
<tr>
<td>Pakistan</td>
<td>2,050,000,000</td>
<td>620,000,000</td>
</tr>
<tr>
<td>India</td>
<td>17,400,000,000</td>
<td>800,000,000[16]</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>1,800,000,000</td>
<td>162,000,000</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>501,000,000</td>
<td>153,000,000</td>
</tr>
<tr>
<td>South-Eastern Asia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cambodia</td>
<td>300,000,000</td>
<td>41,000,000</td>
</tr>
<tr>
<td>Indonesia</td>
<td>8,000,000,000</td>
<td>2,000,000,000</td>
</tr>
<tr>
<td>Myanmar</td>
<td>120,000,000</td>
<td>50,000,000</td>
</tr>
<tr>
<td>Philippines</td>
<td>3,500,000,000</td>
<td>900,000,000</td>
</tr>
<tr>
<td>Thailand</td>
<td>4,300,000,000</td>
<td>1,150,000,000</td>
</tr>
<tr>
<td>Vietnam</td>
<td>3,000,000,000</td>
<td>750,000,000</td>
</tr>
<tr>
<td>Oceania</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>13,590,000,000</td>
<td>90,000,000</td>
</tr>
<tr>
<td>New Zealand</td>
<td>1,040,000,000</td>
<td>8,500,000</td>
</tr>
</tbody>
</table>

\[16\] Including US$ 200 million of counterfeited trademarks
Appendix 2 -

Incidents available (Check-list from Safe medicines.org)

Dr. David Fishman of Ohio Sentenced to Probation in Misbranded Cancer Medicine Case: November 19, 2013

Florida Man Sent to Prison for 2 Years for Selling Unapproved Imported Cancer Medication: October 18, 2013

7 Ohio Oncologists Charged with Illegally Importing Non-FDA approved Cancer Medication: August 13, 2013

Kentucky OBGYN Sentenced to Probation For Purchasing Counterfeit IUDs: August 12, 2013

Clandestine Pharmaceutical Distributor in Virginia That Posed As Canadian Company Shuttered, 11 Indicted: August 7, 2013

Utah Businessman Sentenced to Year in Prison For Importation of Non-FDA Approved Medicines: July 31, 2013

British Owner of Fake Cancer Medicine Distributor Sentenced in Federal Court: July 11, 2013

La Jolla Doctor Sentenced to Probation, Required to Pay over $2 million in Fines For Purchasing Misbranded Cancer Medication: July 2, 2013

Tennessee Cancer Doctor Sentenced to 2 Years in Counterfeit Cancer Medicine Case: June 10, 2013

French Customs Seizes 1.2 Million Doses of Counterfeit Aspirin: May 25, 2013

Tennessee Pharmacist Pleads Guilty to Supplying Dialysis Clinics with Misbranded Chinese Iron Sucrose: May 21, 2013

London Raid Finds $750K in Misbranded Medicines: April 23, 2013

Chicago Pharmacist Charged with Substituting Chinese Counterfeits for Genuine Medication: April 18, 2013


4 Welsh Residents Sentenced in UK Counterfeit Medicines Case: March 27, 2013

Founder of Montana Healthcare Solutions Pleads Guilty in Counterfeit Cancer Medicine Case: March 23, 2013

Portuguese National Sentenced to 44 Months in Jail after $2.4 Million Worth of Unlicensed and Class C Medicines Seized by MHRA: February 25, 2013

Brother of Lebanese State Minister Arrested in Counterfeit Medicines Case: February 15, 2013

7 Sentenced in China For Producing Toxic Gel Medicine Capsules: February 6, 2013

3rd Instance of Counterfeit Cancer Treatment Found in United States: February 5, 2013

Puerto Rican Man Sentenced in US Counterfeit Medicines Case: January 28, 2013

Canadian Citizen & Online Pharmacy Entrepreneur Sentenced to 4 Years in Counterfeit Medicines Case: January 9, 2013

Fake Doctor Pleads Guilty to Practicing Without a License & Administering Unapproved Medicines in San Diego: October 19, 2012

New Zealand Citizen Pleads Guilty in US Counterfeit Medicine Case: July 19, 2012

Angola Customs Agents Find Vast Store of Fake Malaria Medicines in China Shipment: June 1, 2012

MHRA Seizes £14 Million in Assets from Convicted UK Medicine Counterfeiter: April 27, 2012

Two Israeli Citizens Plead Guilty to Importing Counterfeit Medicines to US: April 24, 2012


San Diego Pharmacist Pleads Guilty in Misbranded Cancer Medicine Scam: March 8, 2012

La Jolla Businessman, James R. Newcomb, Pleads Guilty to Counterfeit Medicine Importation Charges: February 22, 2012

Saint Louis Area Oncologist Pleads Guilty to Purchasing and Distributing Fake Cancer Medicines: February 16, 2012

Counterfeit Cancer Treatment Medicine Found in United States: February 14, 2012

Maryland Oncologist Pleads Guilty to Importing Misbranded Cancer Medicines: August 8, 2011
Counterfeit Cancer Medicine Ring Exposed In Chinese Trial: May 20, 2011
Man Found Guilty of UK’s Biggest Fake Medicine Case Sentenced to 8 Years, Faces Over $8 Million in Fines: April 8, 2011
Counterfeit Pills Infiltrated Over-The-Counter Nutritional Supplement Market: February 22, 2011
Deadly Over-The-Counter Fake Medicines Distributed to Americans: January 29, 2011
Philadelphia Resident Admits Selling Over-The-Counter Counterfeit Medicines Containing Carcinogenic Solvents: May 10, 2010
Feds Shut Down Rogue Online Pharmacy Operating Out of Kansas City: February 15, 2011
Suburban Chicago Businessman Arrested in Alleged Fake Medicine Importation Ring: December 13, 2010
Rhode Island Woman Convicted of Importing and Selling Fake Prescription Medicines: February 9, 2011
Missouri Man Sentenced for Selling Thousands of Fake Pills: February 7, 2011
Counterfeit Weight-loss Medicine Smuggling leads to 2 Guilty Pleas and Serious Health Incident: January 28, 2011
New Zealand Resident Arrested In International Counterfeit Medicine Ring: January 26, 2011
Belgian Citizen Pleads Guilty to Selling Counterfeit Medicines in US via Online Pharmacy: January 21, 2011
Israeli Authorities Catch Smuggler with 5,000 Counterfeit Pills: October 20, 2010
Counterfeit Medicine Found in German Pharmacies: August 12, 2010
$12M in Counterfeit Medicines Seized in Southeast Asia: February 8, 2010
Mapping the World of Counterfeits: November 6, 2009

Counterfeit Antimalarial Medicines Found in Ghana: September 29, 2009
Medical Sales Representative Caught Selling Fake Flu Vaccines: August 30, 2009
Counterfeit Medicine Ring Busted in Montreal: August 30, 2009
Counterfeit Medicines Seized in Kenya: August 30, 2009
2 Million Counterfeit Needles Found in Europe: August 30, 2009
Study: Counterfeit Antimalarials Discovered in Southeast Asia: August 30, 2009
Counterfeit Insulin Needles Found in the UK: August 30, 2009
MHRA Seizes Fake Medicines in England: August 30, 2009
Counterfeit 'Lifestyle' Medicines Uncovered in Indonesia: August 30, 2009
Nigerian Children Killed by Contaminated Teething Medicine: August 30, 2009
Counterfeit Heparin Blamed for Worldwide Deaths: August 30, 2009
Thousands of Fake Pills Removed from UK Pharmacies: August 30, 2009
Southern California Oncologist Convicted in Cancer Medicine Importation Scheme: May 11, 2009
Fake Botox Sickens 4, Arizona Suppliers Land in Jail: January 26, 2006
109th Congress Discusses the Tragic Death of Missouri Cancer Patient Given Counterfeit Medicines: November 1, 2005
4 Deaths Tied to Counterfeit Medicines Dispensed at Ontario, Canada Pharmacy: September 9, 2005
References

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