

Counterfeit medicines a world problem

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BACKGROUND

Since man began to brew potions, ointments and medicinal plasters to fight disease, adulterated products also appeared. Queen Hatshepsut of Egypt (circa 1500 BC) commissioned an expedition to search for genuine herbs, as the Egyptian markets were flooded with fake botanicals.⁽¹⁾

Around the 4th century BC, Theophrastus Eresos (circa 372 AC–286 BC), friend of Aristotle and follower of his philosophical works and the first great botanist known warned in his work of fake medicines of botanical origin.⁽²⁾

Three centuries later, the Greek Pedanius Dioscorides (40 AC–90 AD), surgeon, pharmacologist and botanist, who accompanied the Roman armies as doctor wrote his famous work "De materia medica". Translated into at least 7 languages and used as pharmacology text for more than 15 centuries, these writings



De materia medica by Pedanius Dioscorides

not only describe the medicinal value of plants, chemicals and natural products, but also point out the existence of a market of falsified medicinal products.^(3,4)

In England from the end of the 17th and during the 18th century, patent medicines grants were given by the kings.⁽⁵⁾ The name patent medicine is utterly misleading since there was no need to reveal their components or effectiveness; owners only paid to have a patented brand. Richard Stoughton's Elixir was one of the first compound medicines thus recognized. These early drug

attempts constituted mixtures of water, with any part of plants (stems, leaves, roots, seeds, fruits and flowers), spices, alcohol (as a solvent and preservative) and sometimes sugar. Today some of these products are still used as flavoring for drinks or



Label for Dr. Stoughton's Elixir manufactured in USA by Dr. Jos Frye.

Label from Lydia Pinkham's Herb Medicine.

Different products from the Kickapoo Indian Co.

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An old apothecary's laboratory.(6)

bitter or sweet cordials and liqueurs to aid digestion after meals. In 1906, the first law to regulate the safety and effectiveness of medicines in the United States (the Pure Food and Drug Act) was enacted.(7) Throughout the twentieth century, but especially in its second half, the progress in basic and medical sciences and the development of technology in the pharmaceutical industry gave rise to the pharmacopoeias, which regulate the production processes and quality control of drugs.

Since the creation of the World Health Organization (WHO) in 1948 some experts expressed concern about the quality of medicines in the international market.(8) In 1951 the Executive Committee of WHO adopted resolution EB7.R79 requesting the Director-General to take into account the need for more uniform methods of drug control in the interests of health and international trade.(9)

According to the WHO,(10) the global market for pharmaceuticals is equivalent to \$ 300 billion USD per year, a figure that should increase to 400 billion dollars in the next three years. The 10 largest pharmaceutical companies control more than a third of this market, some with sales of more than \$ 10 billion USD per year and 30% margins. Six of these companies are based in the United States and four in Europe. It is expected that North America, South America, Europe and Japan will constitute 85% of the world pharmaceutical market through most of the 21st century.

The first cases of presumably fake, poor quality and counterfeit drugs were reported to the World Health Organization since the early 80s.) In November 1985, WHO organized a meeting on the rational use of drugs in Nairobi, Kenya, where the topic of counterfeit medicines was discussed.(11) In May 1988, the World Health Assembly issues its Resolution WHA 41.16,(12) requesting WHO to initiate programs for the prevention and detection of counterfeit and substandard pharmaceuticals. The first international meeting on counterfeit drugs was organized by WHO in 1992.

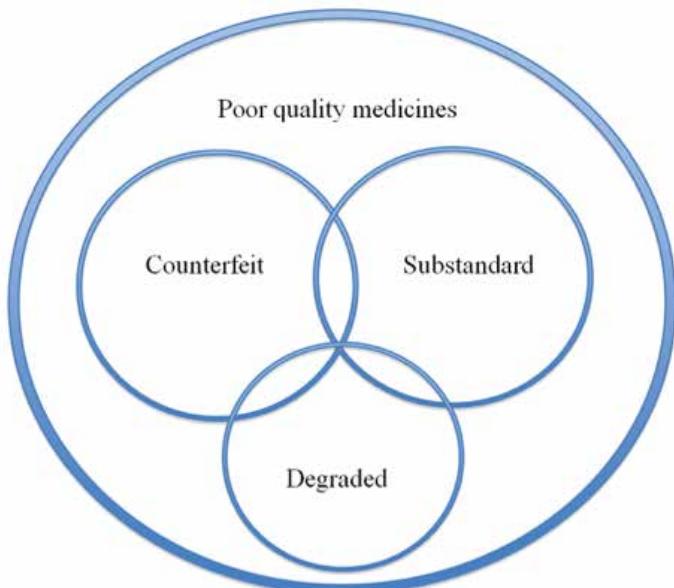
The Declaration of Rome (February 2006, after the WHO Inter-

national Conference ("Combating Counterfeit Drugs: Building Effective International Collaboration") declares that:(13) "Counterfeiting medicines, including the entire range of activities from manufacturing to providing them to patients, is a vile and serious criminal offence that puts human lives at risk and undermines the credibility of health systems."

As a result of this meeting, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT)

composed of 193 Member States of WHO was established on a voluntary basis and includes national and international organizations, agencies responsible for enforcing laws and regulations, drug regulatory authorities, customs and police organizations, non-governmental organizations, associations of pharmaceutical manufacturers and wholesalers, health professionals and patient groups, with the intention of making the national authorities and decision-makers in each country to establish effective legislative measures to combat drug counterfeiting.

"Poor quality medicines" is a term inclusive of counterfeit, sub-



Venn diagram illustrating public health-oriented definitions of poor quality medicines.

standard, and degraded medicines and also for medicines that fail chemistry analysis but with insufficient information to determine whether they are counterfeit, substandard, or degraded. The available data do not allow relative sizing of the area of

each circle in proportion to the frequency of type of poor quality medicine. There could be grey areas between all three main

types. For example, both substandard medicines and counterfeits could become degraded after manufacture.(15)

Definition of Counterfeit Medicines

IMPACT in its 2008 meeting, together with WHO, gave a very comprehensive definition of counterfeit medical products:(14)

The term counterfeit medical product describes a product with a false representation (a) of its identity (b) and/or source (c). This applies to the product, its container or other packaging or labeling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components (d), with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.

Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country, but authorized elsewhere are not considered counterfeit. Substandard batches of, or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting.

Notes:

- (a) Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behavior shall be considered during the legal procedures for the purposes of sanctions imposed.
- (b) This includes any misleading statement with respect to name, composition, strength, or other elements.
- (c) This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution.
- (d) This refers to all components of a medical product.

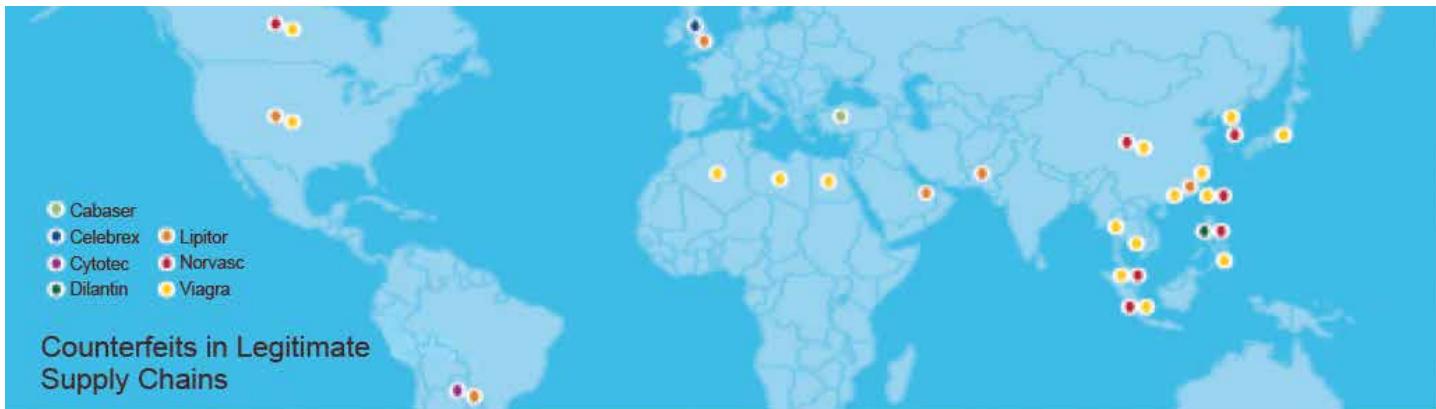


Counterfeit drug manufacture without sanitary or quality regulations.
(17)

WHY DO COUNTERFEIT MEDICINES EXIST?

The main reason behind this business is the huge profits and high demand for drugs. For counterfeiters, cost of ingredients is low because they use less, use cheap substitutes or totally omit them, as often happens. Production does not require the construction of large infrastructure or facilities, it can be done in cottage industry, patios and warehouses without proper sanitation. There are no costs for quality assurance or compliance with Good Manufacturing Practices (GMP), taxes are not paid and as a result margins are very high in a market of \$ 60 billion USD. (15)

The lack of Good Distribution Practice of human and veterinary



Map of Pfizer counterfeited medicines found in distribution chains in different countries (18)

medicines facilitates the entry of counterfeit drugs in the distribution chain. WHO estimates that:

- only 20% of countries have well-developed systems of pharmaceutical regulation;
- 50% have varying degrees of effectiveness in regulating drugs;
- the remaining 30% have a shortage of regulations to control drugs or no compliance is required. (19)

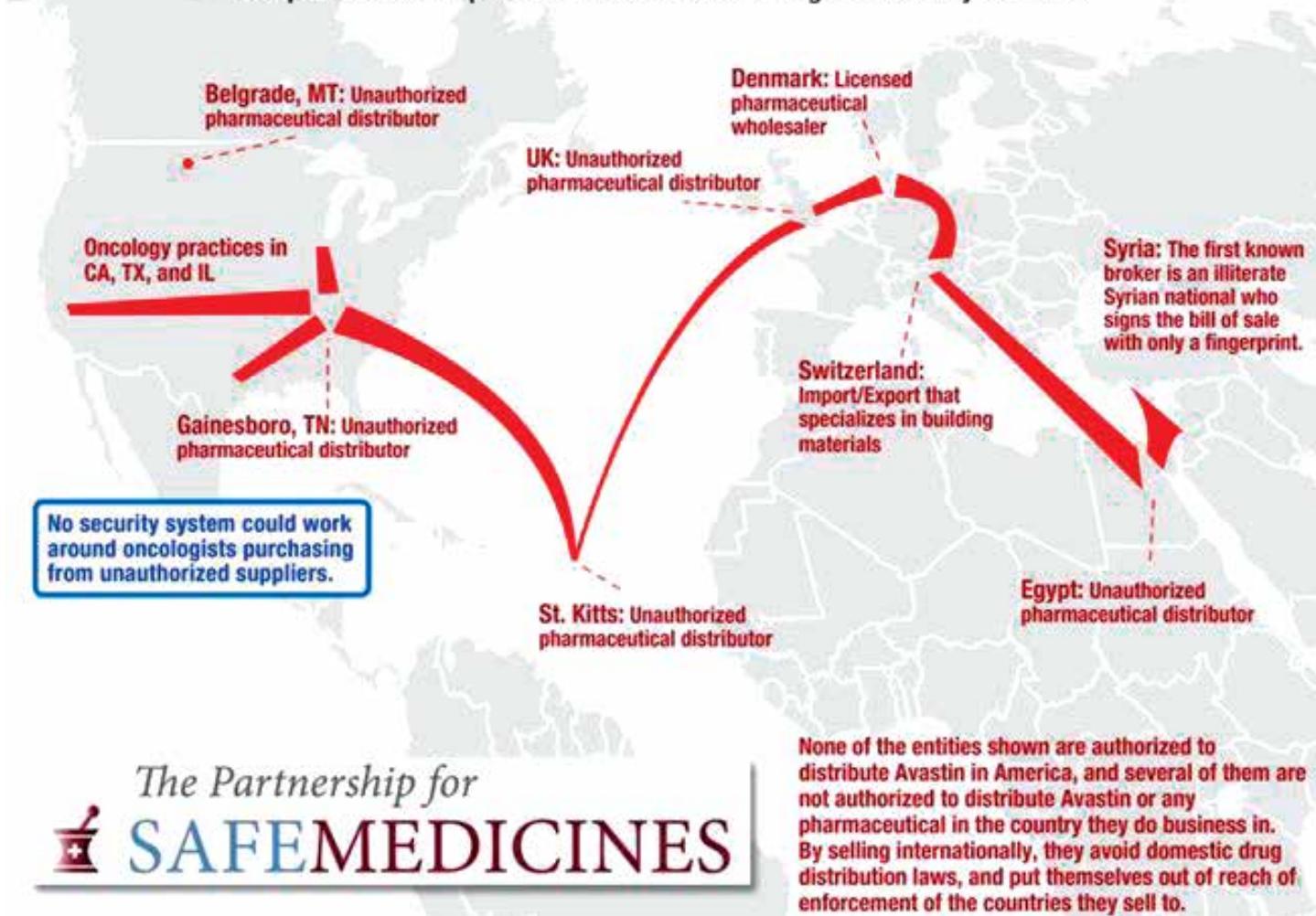
DISTRIBUTION ROUTES

Some countries tend to control pharmaceuticals for export less than the medicines consumed locally.

Free zones are also less controlled and become an opportunity for the illegal drug market.(20) Today the complex trade routes, where products go through several zones and dozens of countries, makes it difficult to determine the exact origin of a coun-

Counterfeit Cancer Medicine in the US. How Can This Happen Here?

The path of ownership of counterfeit anti-cancer drugs on their way to the US.



Often the counterfeit medicines "wander" through several countries (sometimes dozens) before reaching their final market. (22)

terfeited drug. The more complex a trade route is, the easier it is to introduce counterfeit medicines. As there is a trend towards complex global trade routes and the use of free zones due to their fiscal and logistical benefits, options for inserting illegal goods in the supply chain of any country are many and easy. (21)

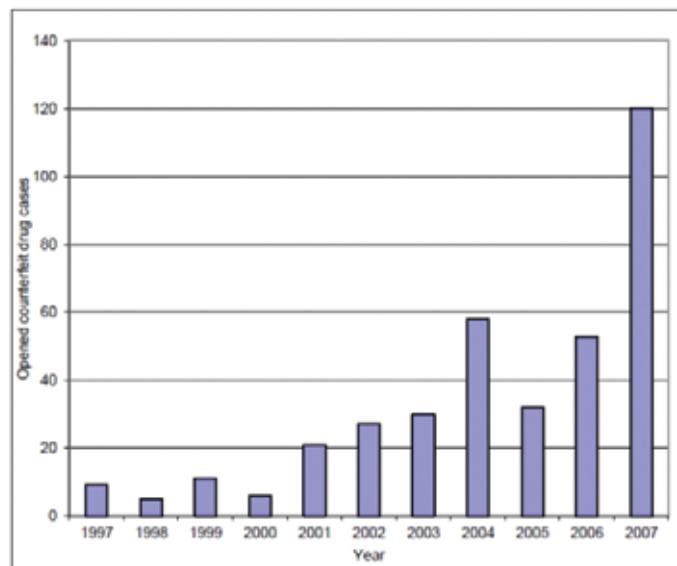
EXTENT OF THE PROBLEM

There are no accurate data to measure the extent of this vast, sophisticated and lucrative business accurately, but we are talking about large quantities of drugs seized in various parts of the world. "There is a flow of products coming from everywhere and going to everywhere, there are so many hubs", says Aline Plançon Interpol officer.(23)

The most reliable sources of data on counterfeiting are the WHO and the International Medical Products Anti-Counterfeiting Taskforce (IMPACT).

It is estimated that in developed countries (EU, USA, Canada, Australia, New Zealand and Japan), less than 1% of medicines sold are fake, while in less developed countries this figure is above 10%. In some countries of Africa, Asia and Latin America, the counterfeit drugs may account for more than 30% of the market. In internet it is considered that 50% of the medicines sold are fakes.(19,20,24)

The graphic shows some stability in the number of new cases of counterfeit drugs found in the US market until 2000 and exponential growth after 2001 (graphic 1).



Graphic 1. Increased detection of counterfeit medicines in USA between 1997 and 2007(20,25)

In 2009, 20 million pills, bottles and bags of fake and illegal drugs were seized in a five-month operation coordinated by the International Criminal Police Organization (Interpol) through China and seven Southeast Asian neighbors; 33 people were arrested and 100 sales outlets closed.(23)

In Europe, customs officials seized 34 million counterfeit pills in just two months in 2009, Guenter Verheugen Commissioner of the European Union said it "exceeded our worst fears."(23)

In 2008, in Egypt counterfeit drugs worth hundreds of millions of dollars were found and a network that supplied to consumers across the Middle East was deactivated. (23)

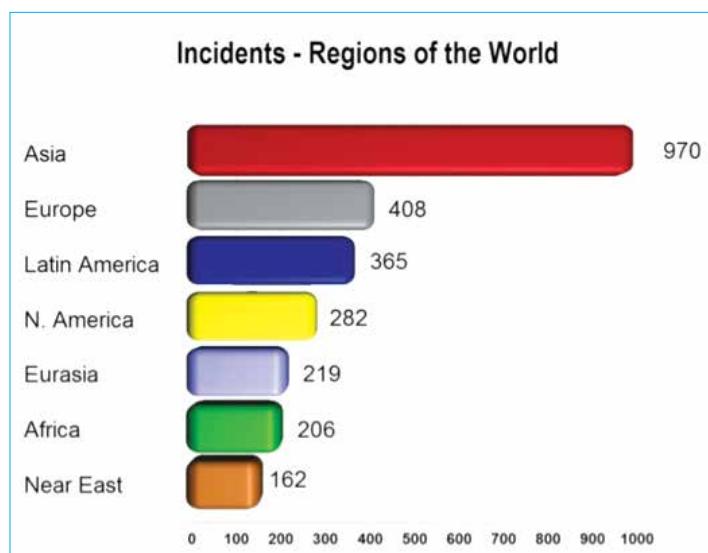
(23)

A major concern for the entire Asian region is the high prevalence of counterfeit drugs against malaria. (Antimicrobial resistance in developing countries) The highest prevalence was reached in Southeast Asia and the Mekong Delta, where various studies suggest that between 38% and 68% of the market consists of fake and absolutely useless artesunate. (27)



The left box corresponds to the fake artesunate (27)

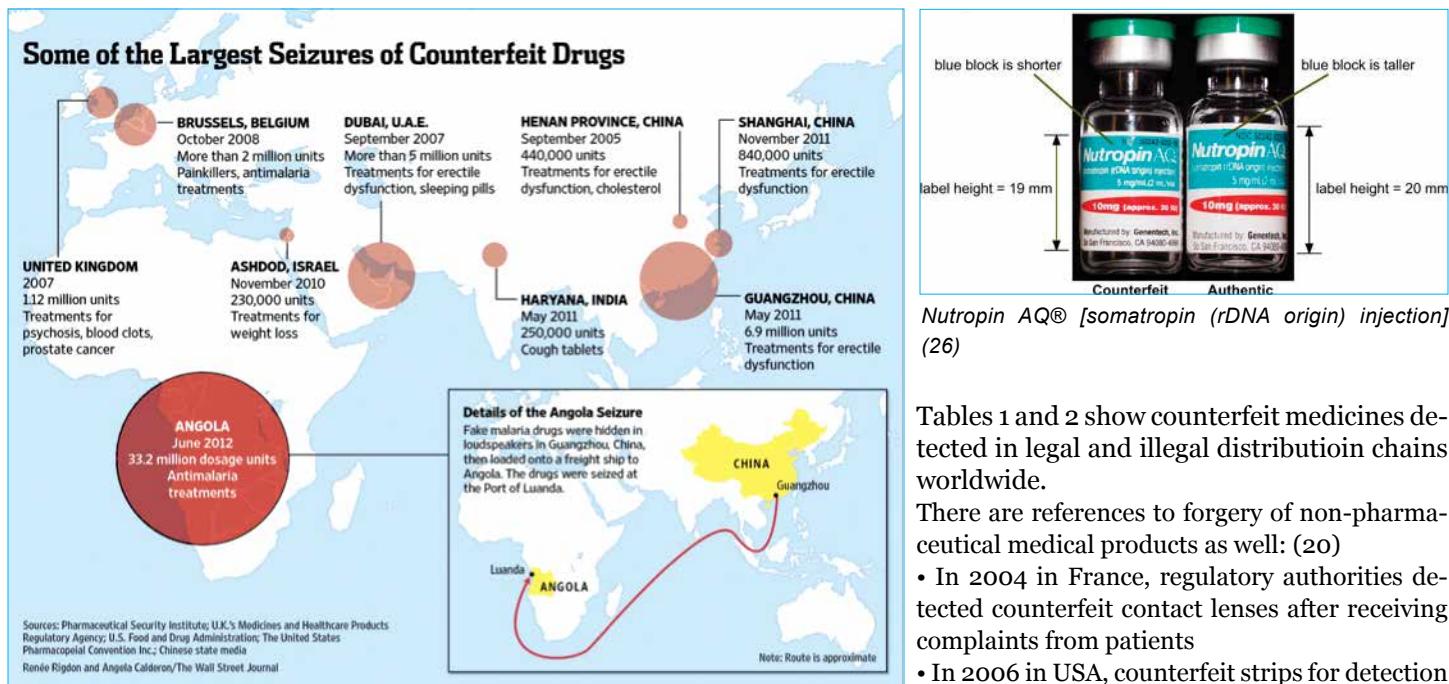
The Pharmaceutical Security Institute (Pharmaceutical Security Institute) considers Asia a major source of counterfeit drugs, but some Asian countries are also the largest sellers of legitimate medicines, various sources indicate that up to 90% of legitimate drugs used in western countries originate in China (see graphic 2).(28)



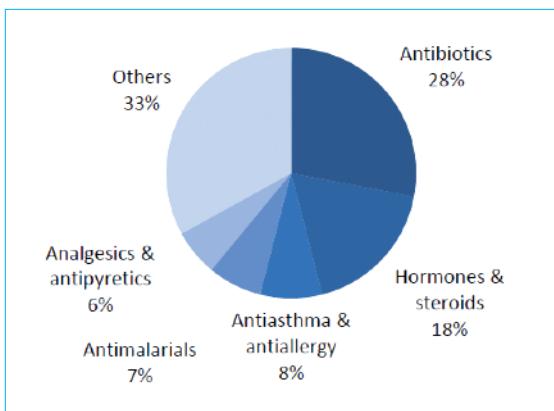
Graphic 2. Numbers of counterfeit drug detection in 2013 and its extent by regions according to the PSI

Asia shows the highest incidence, since it is producer and consumer of counterfeit medicine. In Europe and North America counterfeit drug detection shown is the result of tight control methods in their health systems. In other regions, such as Latin America and Africa it is possible that there are more problems of counterfeit medicines and the figures are higher than those shown above, because the regulatory agencies are more permeable and there are less stringent regulations.

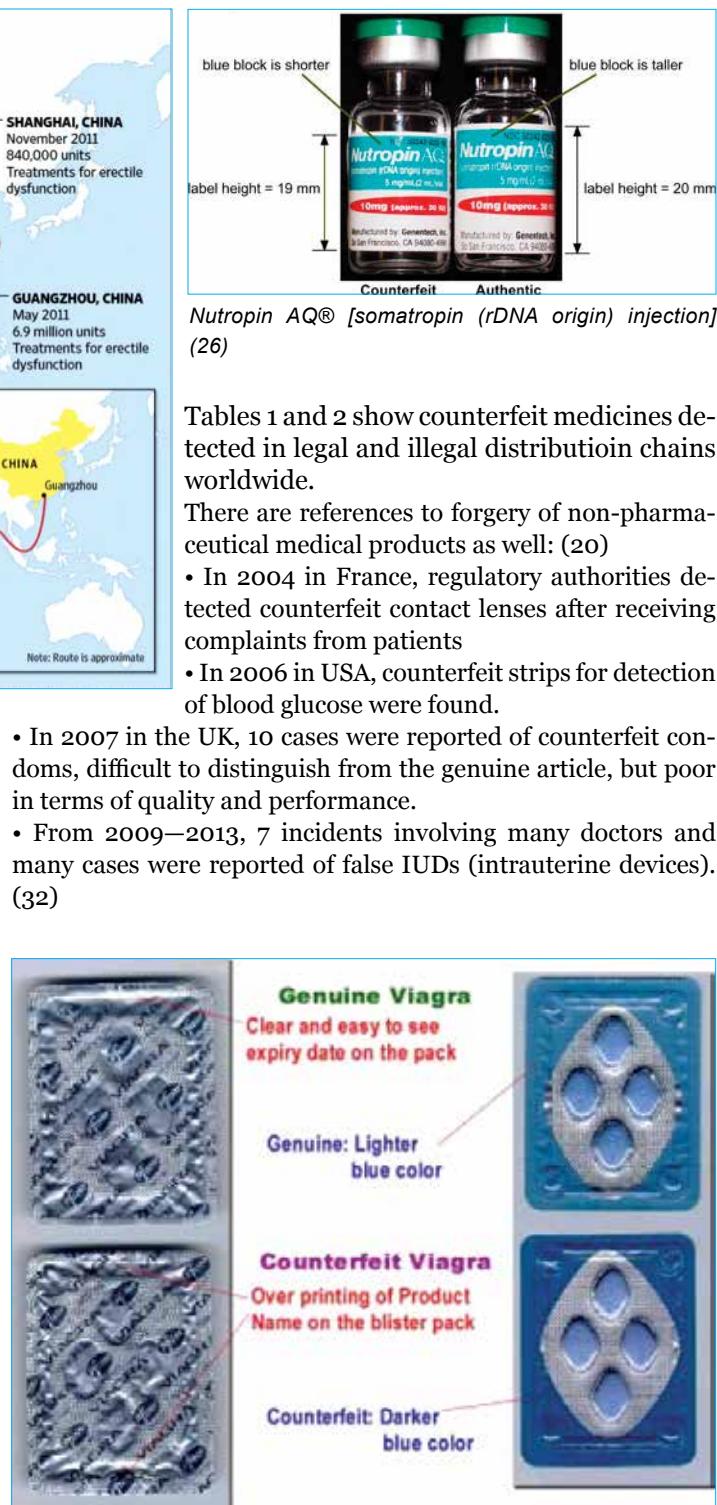
The graph below shows according to the Wall Street Journal some of the biggest captures of counterfeit medicines.(29)



Until recently, the trend was that in developed countries especially the “lifestyle” (weight loss and erectile dysfunction drugs, vitamins, etc.) medicines were falsified. Today these differences are being erased and any counterfeit medicine appears in any country. (30)



Graphic 3. Counterfeit pharmaceutical classes reported to the WHO between 1999 and 2002(20)



CONSEQUENCES

Needless to say, the serious consequences in economic losses and material resource expenses that this scenario implies for pharmaceutical companies, drug distributors, health authorities and governments in general, and although somewhat different, for patients, whose lives are endangered.

Table 1. Counterfeit medicines detected in the legal distribution chain of Great Britain that were recalled(31)

Date	Product	Batch number	Alert	Location
May 2009	Seretide 250 Evohaler 8mL	1183R - 06/2009	EL(09)A/12	GB distribution chain
July 2007	Sensodyne Original and Sensodyne Mint 50mL tubes	Prod 07/2005 Exp: 08/2008	EL(07)A/13	GB distribution chain
June 2007	Plavix 75mg Casodex 50mg	3103/1 to 3103/20 Exp: 07/2009 65520 - 07/2011	EL(07)A/09 EL(07)A/08	GB distribution chain
May 2007	Plavix 75 Zyprexa 10mg	3098 - 08/2008 6Y098 - 07/2009 A200127 - 02/2009	EL(07)A/07 EL(07)A/06	GB distribution chain
July 2006	Lipitor 20mg Propecia	004405K1 - 11/2007 243828, Exp: 06/2007	EL(06)A/16	GB distribution chain
February 2006	Viagra	2183401, Exp: 10/2008	No alert issue	Illegal distribution chain
September 2004	Reductil 15mg	65542 - 01/2007	EL(04)A/08	GB distribution chain
August 2004	Cialis 20mg	A041410 - 06/2006	EL(04)07	GB distribution chain

Table 2. Other counterfeit drugs detected in different countries(31)

Date	Product	Batch number and expiry date	Location
August 2013	Gentamicin 80mg iny Biviol Postinor 0.75mg	L12020299 Exp: 03/2015 920569 T13073C, T54365E, T99128L, T12104B	Guatemala distribution chain Germany distribution chain Illegal distribution chain
July 2013	Postinor 2 levonorgestrel tablet, 0.75mg Sulfadoxina 500mg/ Pirimetamina 25mg Sutent	T13073C, T54365E, T99128L, T12104B 1833, Exp: 02/2014 T737E, Exp: 03/2015 U299B, Exp: 10/2015	Nigeria distribution chain Illegal distribution chain Rumania and Germany Distribution chains
June 2013	Cialis 20mg Viagra 100mg	05668 B314833021	Illegal distribution chain Illegal distribution chain
May 2013	Suustanon 250	3CSH550	Illegal distribution chain
March 2013	Omeprazole 20mg	BZ4333 E008 E018 G003	Germany distribution chain
February 2012	Altuzan 400mg/16mL	B0621, Exp: 10/2012	USA distribution chain
April 2011	Cialis 20mg	05668, Exp: 04/2013	Illegal distribution chain
February 2011	Prograf 1mg Viagra 100mg	1C6371C, Exp: 03/2012 1C6512A, Exp: 02/2012 1D4434A, Exp: 06/2012 314833201, Exp: 01/2014	Ireland distribution chain Ireland distribution chain Illegal distribution chain

* Warning: this code can be searched online



From Inside Pfizer's Fight Against Counterfeit Drugs (33)

- In Singapore in 2008, 150 people were admitted for severe hypoglycemia; four of them died and 7 suffered irreversible brain damage. They had used erectile dysfunction pills containing glyburide.(20)
- Between 2007 and 2008, a contaminated blood thinner, heparin, was linked to 149 deaths in the United States. (34)
- In October 2012, contaminated steroids near Boston, USA, killed 11 patients by fungal meningitis and more than 100 became sick. (34)
- In 2012, some vials of the cancer drug Avastin did not contain any active ingredient. (34)
- In Belgium and Germany, counterfeit heparin possibly led to 81 deaths and hundreds of side effects in patients.
- In December 2004, in Argentina, a 22 year-old pregnant woman with slight anemia died of liver failure after receiving injections of a counterfeit iron supplement in a public hospital. Two other women also died after receiving the counterfeit product and a dozen other women were less affected. (35)
- During a meningitis epidemic in Niger in 1995, more than 50,000 people were inoculated with fake vaccines that caused 2,500 deaths. The vaccines were a gift from a country that considered them to be genuine. (36)
- In Haiti, in 1995, 89 children died and 30 more children died in India in 1998, due to ingestion of cough syrup with acetaminophen made with diethylene glycol (a toxic chemical used as antifreeze substance).



Stand in African market selling medicines (37)

Limitations

This review presents only some data extracted from the literature, however, this problem is large when you consider:

- Lack of information on counterfeit drugs that exists in all institutions involved in the production, distribution and use of drugs.
- A dynamic market that adjusts to patients' tendency to get more economical products, with total unawareness of the consequences to their health."

CONCLUSIONS

Counterfeit medicines exist since time immemorial. Now they have turned into a far greater scourge, since it has become a very lucrative business, easy to carry out and with relatively few restrictions. The trend is for the market of counterfeit drugs to increase every year.

There is no simple solution or a standard for all countries to eliminate this problem. Each country has to develop a strategy based on its particular situation, taking into account the available infrastructure and human resources.

Drugs that are most likely to be falsified are those from international laboratories with great market demand and high cost, which guarantee a high volume of business with attractive prof-



Pictured in 2007, Jean-Pierre Braganti, regional security director of Sanofi-Aventis, displays boxes of counterfeit (right) and genuine (left) Plavix pills during a press conference in the United Arab Emirates (38)

its for counterfeit medicines.

International pharmaceutical laboratories organize the distribution of legitimate medicines worldwide through business groups serving different geographic areas. This organization not only reduces the cost of drugs to the patient, but also guarantees pharmacovigilance of each batch of drug produced and marketed. The accredited distributor, who represents a pharmaceutical laboratory, is also responsible before the country's health authorities of addressing any problems that arise with the drugs he markets and establishing direct communication between the health authorities and the manufacturing laboratory. The drugs sold by authorized distributors are safe and reliable products.

The existence of counterfeit drugs in the health system or private distribution networks of any country are a challenge and a possible disrepute for health professionals and institutions in which they work. During the daily exercise of their profession, they can make a proper diagnosis and indicate the appropriate therapy to a patient; however, if the person acquires a counterfeit drug in the market and does not get the expected results, he



Modern biopharmaceutical manufacturing plant (39)

may consider that the physician is not properly trained and seek a second opinion. This example may become constant if patients are not properly directed on the medicinal products they should acquire, with which the physician is sure of the effectiveness and safety of the product.

According to the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the stability of drugs should be assessed according to the climate zone in which they are to be used: Zone I (temperate zone), Zone II (Mediterranean/subtropical zone), Zone III (hot dry zone), and Zone IV (hot humid/tropical zone). This means that for a drug manufactured for zone I, II or III, the effectiveness of its active ingredients is not necessarily guaranteed during its entire shelf life in a zone IV country (Central America). Medicines without stability analysis in zone IV are not considered counterfeits; however, their effectiveness may be compromised in climates with high temperature and humidity



Present day drug quality control laboratory(41)

(zone IV).(40)

In Belize, the Ministry of Health is already working on the organization of a pharmaceutical registration. It has established a system of pharmacy inspections to ensure better control of the distribution and use of medicines in the country. However, everyone involved in the health system (importers, distributors, doctors and pharmacists) are responsible for providing reliable, safe and effective medicines to the population.

Public health is everyone's responsibility; nowadays, the ease with which we travel from one point to another of the planet makes us more vulnerable and we must be prepared, it is essential to have the right medicines to meet any emergency.

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Cooperation

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