# Counterfeit drugs: definitions; origins and legislation

*Elisabethann Wright*

**The subject of "counterfeit drugs" is becoming one of increasing concern throughout the world. Recent statistics from the Council of Europe suggest that 44% of products marketed on the internet as Viagra is counterfeit. Of even greater concern is the belief that 95% of all medicines sold over the internet are unsafe, says Elisabethann Wright.**

According to the European Commission, counterfeiting in general represents around 5-7% of world trade.[1] This estimate demonstrates the enormous proportions of the issue and reveals the economical interest of black market drug makers. The annual earnings from the sales of counterfeit and substandard medicines are estimated at over US$35bn (€27bn) globally.[2] As much as 15% of the global medicines supply chain could, at any time, be counterfeit. This percentage is much higher in certain regions, particularly less developed countries.[3] According to the World Health Organisation (WHO), the share of the total medicines supply constituted from counterfeit drugs is estimated at 20% for Russia, 40% for Mexico and as much as 80% for Nigeria.[4] Moreover, WHO believe that substandard or ineffective medicines have contributed to the emergence in developing countries of drug-resistant strains of cholera, salmonella, tuberculosis and other diseases.[5] A 2003 report by Michele Forzley of the International Intellectual Property Institute (IIPI) compiled data from numerous sources and found reports that more than 1,000 hospital admissions resulted from counterfeit insulin in Russia.[6]

There is, however, no one single definition used globally; different definitions are employed depending on regulator and context. The fact that a global uniform definition is yet to be adopted is frustrating efforts to coordinated global actions and intelligence sharing. Establishing a common terminology would therefore appear to be a priority for the world community.[7] The absence of a universally accepted definition of what constitutes a counterfeit drug creates obstacles to the exchange of information between countries. It also limits the current possibility to understand the true extent of the problem at a global level.

There are a variety of different types of drug "reproduction" that can fall within the definition of counterfeit drug. These include drugs that are manufactured out-of-hours in the same facility as official production, using the same formula and, often, raw materials from the same source. Drugs are also known to be manufactured using the same formula and active ingredients but in a different facility. Then there are what are most traditionally perceived as counterfeit drugs. These are products manufactured using the same active ingredient but in different proportions, and/or of a lesser quality. Products most commonly perceived as counterfeit drugs are those that contain none of the active ingredients of the original product, with either a different active ingredient or, on occasion, no active ingredient at all being used in their production.

The WHO has categorised counterfeit drugs into seven categories. These include i) fake packaging, correct quantity of correct ingredient (clone); ii) fake packaging, wrong ingredient; iii) fake packaging, no active ingredient; iv) fake packaging, incorrect quantity of correct ingredient; v) genuine packaging, wrong ingredient; vi) genuine packaging, no active ingredient and vii) genuine packaging, incorrect quantity of correct ingredient.[8]

Moreover, in order to address the problem of counterfeit drugs the World Health Organization as developed the following definition:

*"counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."*

An alternative definition developed in a report prepared by the parliamentary assembly of the Council of Europe (CoE) defined counterfeit as "deceit". It is something that has been forged, copied or imitated without the perpetrator's having the right to do so, for the purpose of extracting money from credulous or consenting consumers.

If the two definitions are to be interpreted literally, that devised by the Council of Europe might arguably be considered to be the most accurate, given that it covers both labelling and manufacture. However, both definitions are based on the same fundamental element; counterfeit drugs are manufactured and marketed by those who intend to deceive and mislead the consumer. What is clear is that, by definition, there are no "good quality" counterfeit drugs since counterfeits are products whose true identity and/or source is unknown.

It is unquestionable that internet sales, the most commonly known source of counterfeit drugs, have contributed greatly to their increase on the world market in recent years. However, illegal internet trade is only one part of the story. Counterfeits are also made into the legitimate medicines supply chain in Europe. Although a large share of the counterfeit drugs in Europe are sold via the internet and on the black market, there is evidence that counterfeiting hits the legitimate supply chain of medicines as well. What is a cause for concern is that such incidents seem to be part of counterfeiters' very deliberate strategies.[9] According to the European Commission, between 2001 and 2005, the EU experienced 27 incidents involving such counterfeit drugs.[10] In July 2005, fake versions of Pfizer's cholesterol-lowering drug Lipitor (atorvastatin) were found on the regular market in the UK. Responding to the findings, the UK regulator, Medicines and Healthcare products Regulatory Agency (MHRA) issued recalls of the medicines. Over 50% of the returned Lipitor drugs were found to be counterfeit.

The European Commission has recently reported a surge in illicit drugs found trying to access the EU. During 2005, 500,000 counterfeit medicines were seized at the Community border. It is believed, however, that these represent merely the tip of the counterfeit iceberg.[11] In 2005, customs officials seized around 75

million articles EU-wide, with the number of customs cases involving counterfeit products rising to over 26,000, an increase of 20% on the previous year. In Africa, an EFPIA member company reports that counterfeiting has acquired 60% of its product market. The largest counterfeit market with close proximity to the EU is Russia.

As mentioned, a significant amount of counterfeit goods enters the EU via sales over the internet, which has become an increasingly used purchase tool for European consumers. This is especially the case for so-called lifestyle drugs for which the consumer often is prepared to take health risks to purchase at an apparently lower price than that paid in a local pharmacy and, in the process, avoiding the need of a prescription.[12] The European Commission has noted an increase in online trading of counterfeit drugs purported to treat medical conditions, most commonly obesity and erectile dysfunction.[13] It has also noted a high level of consumption of counterfeit drugs for viral infections (e.g. Tamiflu).[14] In developing countries, counterfeit drugs are common even among more regularly used medicines such as antibiotics.[15] Fake condoms are also widely sold.[16] According to the WHO, both well established generic drugs and innovative medicines are subject to counterfeiting.[17]

### ...the origin of most counterfeit drugs

The biggest exporter of counterfeit products to the rest of the world is, in general, estimated to be China. China is also estimated to be the number one producer of counterfeit drugs.[18] A significant amount of counterfeit drugs is also believed to originate in India. Other sources are perhaps somewhat surprising, including as they do Afghanistan, Guinea and Switzerland.[19]

At the beginning of the '90s, counterfeits were often poor-quality pills produced by small-scale operators with limited means. Today, counterfeiters are able to manufacture nearly perfect pills with the same active ingredients as the originals.

Counterfeiters have grown increasingly sophisticated in particular in China.[20] This did not, however, prevent the tragedy that occurred in 2005 during which more than a dozen infants died in China after their mothers unknowingly fed them fake milk powder that had little or no nutritional value. The incident prompted a pledge from Chinese Vice Premier Wu Yi to adopt severe penalties for counterfeiting and an offensive against counterfeit products, dubbed "Operation Eagle". The yearlong effort culminated in the November 2005 arrests of 419 suspects and the confiscation of more than 100 million yuan, or about €10m, in goods, ranging from car parts to cosmetics and drugs.[21]

China has begun taking steps to address the issue, particularly since its accession to the World Trade Organisation (WTO) in 2001. According to the WHO, China's State Drug Administration closed 1,300 illegal factories and investigated cases of counterfeit drugs worth US$57m (€44m) in 2003 alone.[22]

### ...why is the counterfeit drug market so successful?

The reason for why medicines are targeted by counterfeiters has a lot to do with the fact that fakes can now be made relatively easy. The profitability may therefore be at least as good as for narcotics, while the risk is lower due to lack of rules, law enforcement and global cooperation. Even in developed countries, however, the risk of prosecution and penalties for counterfeiting are still inadequate with the exception of in the US. It is also relatively easy to sell the drugs. On the internet, or in developing countries where the real drugs are expensive, potential consumers are plenty and there is limited regulation and enforcement. The way medicines are traditionally sold also contributes to their potential to be targeted by counterfeiters. The end-user has little or no knowledge of the product and therefore entirely trusts pharmacies, companies and hospitals.[23]

The evolution of social security systems in the western world must also take some responsibility for the success of the market in counterfeit drugs. As states seek to reduce the cost of provision of social security services individuals, particularly those on lower income levels, can see themselves facing increasing drug bills for which they receive less than adequate support. It is almost inevitable that they turn to other, apparently more economical, sources to fulfil their pharmaceutical needs.

The fact that the informed public may be aware of the risks that such an approach presents does not, in the absence of adequate and appropriate information, resolve the problem. Individuals who must face the obligation to pay for their drugs out of pocket often have no access to a reliable distribution system. They cannot afford to pay the normal prices and they resort to alternative sources such as street markets.

The rapidly increasing counterfeiting industry is a threat at many levels. Not only do fake medicines constitute a serious threat to the immediate health of the individual consumer. It also implies macroeconomical costs (tax payers' costs) and costs in the form of loss of confidence in medication and health care systems. Medication with counterfeits may also entail issues that are not defined as injury. Involuntary pregnancies following consumption of fake birth-control pills may not be classified as injury but still pose serious problems, especially in the developing world.

These concerns aside, fake drugs infringe intellectual property rights and cause thereby a divestment of resources from necessary pharmaceutical research and development. This result is also obtained by the fact that reputation of the products involved and consequently the investment made by the innovative pharmaceutical sector is hurt.

### ...the steps taken in the fight against counterfeit drugs

In the EU the control of counterfeit drugs currently revolves around the general regulatory framework of the revised "TAXUD" legislation concerning customs action against goods suspected of infringing certain intellectual property rights.[24] The Regulation identifies two categories of "goods infringing an intellectual property right". Such goods can be *counterfeit goods* meaning goods or trade mark symbols or packaging presented separately, bearing without authorisation, a trademark identical to another trademark validly registered, or which cannot be distinguished in its essential aspects and which thereby infringes the trademark-holder's rights. The second category refers to pirated goods, i.e. goods that are, or contain, copies made without the consent of the holder of a copyright or related right or design right. The main innovations of the new Regulation, as compared to the pre-existed Regulation on counterfeit and pirated goods, include the extension of the Regulation's scope to cover new property rights (including plant varieties, geographical indications and designations of origin) with a view to increasing consumer protection. It also improves the quality of information that must be provided by rights holders to customs when applying for action. Lastly, it facilitates recourse by Small and Medium-Sized Enterprises (SMEs) to the protection of the Regulation (in particular by requiring no fees or guarantees).[25]

The regulatory framework is also complemented with the Directive on the enforcement of intellectual property rights, which aims to harmonise national legislation on enforcement and to establish an effective exchange-system of information between the competent national authorities so as to ensure equality of rights for all rights holders in the EU and to reinforce measures against offenders.[26]

As a practical step towards increasing protection against counterfeit goods in the EU, the European Commission has launched targeted time-limited customs actions at major EU ports and airports. The EU has also established an Anti-Counterfeit Task Force of customs experts to improve targeted customs controls. This Task Force is also aimed at working with industry sectors concerned and third country experts.[27] In addition, the EU is set to introduce an Integrated European Risk Management framework to target and prevent the entrance of high-risk goods at EU borders.[28] There are also increased efforts to share intelligence with third countries, such as the US and China, on trafficking developments and the detection of high-risk consignments.[29]

Within the framework of the CoE, the 46 Member States work towards increasing multilateral cooperation aimed at curbing pharmaceutical crime. Among the steps recently taken was the proposal, during the recent meeting of the Committee of Ministers of the Council of Europe, on 23 and 24 October 2006, that a legal instrument be drafted to combat pharmaceutical crime, counterfeit medicines and other medicinal products included, and to safeguard the health of Europeans. The participants agreed that the elements of the legal instrument should include the definition of pharmaceutical offences as serious crime; penalisation of the manufacture and distribution of counterfeit medicines; establishment of a network of Single Points of Contact in all sectors concerned, especially those of health and law enforcement; adoption at national level of provisions to control the quality of components for pharmaceutical uses, packaging material and manufacturing processes in accordance with the standards laid down by the European Pharmacopoeia; intensified co-operation between law enforcement agencies at national and European level. The participants at the meeting urged all the competent authorities in this field, manufacturers, wholesalers, pharmacists and governmental and non-governmental organisations to combine their efforts to implement effective anti-counterfeiting measures. They also asked the governments of the 46 Council of Europe member states to inform the general public of the risks and consequences of taking counterfeit medicines. ❊



*Elisabethann Wright is Counsel at international law firm Hogan & Hartson's Brussels office*

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[5] Public Safety Jeopardized by Chinese Counterfeiters, Experts Say, at http://usinfo.state.gov/eap/Archive/2005/May/20-45620.html

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[23] Pharmaceutical counterfeiting: Issues, Trend, Measurement, at http://www.oecd.org/dataoecd/42/30/35650404.pdf

[24] Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights

[25] Regulation (EC) No 3295/94 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods

[26] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights

[27] SCRIP, 13 November 2006

[28] SCRIP, 13 November 2006

[29] SCRIP, 13 November 2006

 