



A criminal trade: the EU is set to fight counterfeiting by creating a series of new criminal offences

With the rapid movement of goods in an increasingly global economy, counterfeit products are arriving in ever greater quantities on national markets and posing a major challenge for governments and companies worldwide. Counterfeit goods, according to the World Customs Organization, now account for around 5-7% of international trade. Given the clandestine nature of the business, such estimates can be no more than educated guesses, but there is no doubt that counterfeiting is on the up. The European Commission has responded by proposing a tough new Directive that will compel Member States to impose criminal penalties for counterfeiting that takes place on a commercial scale.

As counterfeit goods flood markets, they undermine companies and economies, depriving governments of fiscal revenue, and often endangering the health and safety of consumers. Some of the goods can even be life-threatening, such as adulterated food, hazardous toys, falsified spare parts for electrical goods, cars or aircraft and, of course, counterfeit drugs.

Counterfeiting is not only an infringement of intellectual property rights, it creates a disincentive for investors and hinders economic development. Today, profits from counterfeit products such as CDs and DVDs are greater than those from heroin. With jail sentences considerably shorter than for drug-related crimes, criminals are finding counterfeiting less risky.

Today, it is widely regarded that the international centre of counterfeiting is China. It has been alleged that at least \$16 billion-worth of goods sold each year inside the country are counterfeit. Procter & Gamble has estimated that 10-15% of its revenues in China are lost each year to counterfeit products.

Most of China's counterfeit products remain in the country, but rising quantities are now destined for foreign markets. This international trade depends on sophisticated distribution networks. Increasingly run by organised-crime syndicates, these networks use many of the same routes that have been established for the trade in narcotics.

Fake pharmaceuticals

More than 10% of the global medicines market is made up of counterfeit products, a trade which not only destroys the health of the people involved, but destroys confidence in the pharmaceutical industry as a whole.ⁱ In response to the growing problem, the European Commission has recently adopted a radical proposal for criminal law provisions to combat counterfeiting. This should help the industry, but not everyone welcomes the political precedent it sets.

It is estimated that up to 25% of the medicines consumed in poor countries are counterfeit or substandard. It is often assumed that the problem isⁱⁱ confined to developing countries, but increased international trade and the global reach of online pharmacies means that the threat of counterfeit drugs reaching the European market is increasing. The World Health Organisation (WHO) has reported that, although 60% of counterfeit medicine cases occur in poor countries, some 40% occur in industrialised countries.ⁱⁱ In 2004, 3% of all counterfeit products seized by customs officials in Europe bore Pfizer's trade mark.ⁱⁱⁱ

The internet is a serious threat to the safety net of national regulatory authorities. Individuals are now able to get anything from *valium* to *viagra* online, and often from websites that are based outside their home country. In 2003, 147, 662 counterfeit *viagra* tablets were seized in the UK alone.^{iv}

The WHO's Commission on Intellectual Property Rights, Innovation and Health cites lack of political will, corruption, conflict of interest, and excessive demand as key causes of counterfeiting in the pharmaceutical industry. It argues for effective regulation, the enforcement of good manufacturing practices and supply chain management systems as essential ways of protecting patients against unsafe medicines.



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The European Commission's proposed legislation is aimed particularly at fake drugs. "Fake" drugs are different to "sub-standard" drugs. Although a drug which contains none, too little or too much active ingredient is ineffective in treating the intended disease, it is possible that such a drug is not counterfeit but is simply defective. This product should be picked up by local regulatory authorities and not allowed on the open market. Unless there is a deliberate action to imitate or attempt to recreate another brand, these drugs are not considered counterfeit. There are numerous ways in which countries and agencies define counterfeits. The WHO defines counterfeit drugs as those:

"which are 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 ingredient or with fake packaging".^v

The key implications for the pharmaceutical industry of the growing trade in counterfeit products are in lost revenue and reputation. Also, pharmaceutical companies can in some countries be held liable for counterfeits of specific products, which can result in expensive and public litigation. In 2002, Serono, a Swiss biotechnology company, settled a case with two American customers who had sued the company (and assorted distributors) after taking a fake version of its body-boosting drug Serostim. The victims claimed that the company should have foreseen the possibility of counterfeits entering the distribution chain and should have taken suitable precautions.

The current regime

At the international level, the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members. Governments are allowed to reduce any short term costs through various exceptions, for example to tackle public health problems. And, when there are trade disputes over intellectual property rights, the WTO's dispute settlement system is now available.

The TRIPs agreement has been characterised by some as a minimal pact lacking sufficient teeth. While TRIPs focuses on the import of pirated products, the proposed EU Directive would enforce counterfeiting legislation with serious criminal sanctions.

In Europe, Directive 2004/48/EC currently regulates the measures, procedures and remedies which can be ordered by Member States' courts in cases of intellectual property infringements. The Directive aims to transpose the provisions of the TRIPs agreement into European law and applies to any infringement of intellectual property rights as provided for by Community legislation (trade marks, Community designs, Community plant variety rights, etc.) and/or by the national laws of the Member States. The objective of the Directive is to ensure a homogeneous level of protection across the Internal Market.

Concerning damages, the European Parliament and the Council had - contrary to the Commissions' original proposal - abstained from implementing the kind of punitive damages that exist under US law. The Directive clearly establishes that the infringer only has to pay civil damages appropriate to the actual prejudice suffered as a result of the infringement.

Member States are allowed to set the damages in two ways: they can take into account all appropriate aspects, such as negative economic consequences, including lost profits which the injured party has suffered, any unfair profits made by the infringer and, in appropriate cases, elements other than economic factors, such as the moral prejudice caused to the right holder by the infringement. Alternatively, they can fix damages as a lump sum on the basis of elements such as the amount of royalties or fees which would have been due if the infringer had requested authorisation to licence or use the intellectual property right in question.

Additionally, courts can order the recall and destruction of infringing goods or injunctions prohibiting the continuation of infringing acts. Alternatively, if a party has acted unintentionally and without negligence, Member States are free to enact regulations which allow the fixing of pecuniary compensation to be paid to the injured party.

Such remedies are already a part of UK law. The EU's proposed new directive goes further though, both in the sanctions imposed, and the political process by which those sanctions will become part of UK law.



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The draft EU Directive

The WHO's definition of counterfeit drugs refers to drugs which “are deliberately and fraudulently mislabelled with respect to identity and/or source”. It is this element of intent that the Commission has seized on.

According to Commission Vice-President Franco Frattini, who is responsible for justice, freedom and security matters, the new provisions proposed by the Commission represent the criminal law dimension of the fight against counterfeiting and piracy in Europe.^{vi} In the draft Directive, all intentional infringements of an intellectual property right on a commercial scale, including attempting, aiding and abetting such infringements, are treated as criminal offences. The “commercial scale” principle stems from Article 61 of the TRIPs agreement. This states:

“Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale”.

The minimum sentence proposed by the new Directive is a term of four years' imprisonment where the infringement is committed under the aegis of a criminal organisation or carries a serious risk to the health and safety of individuals. The threshold of four years' imprisonment was chosen because it broadly corresponds to the criterion used to identify a serious offence.

A risk to personal health or safety where the counterfeit product placed on the market directly exposes people to a risk of illness or accident. This element of the offence is particularly relevant for the pharmaceutical industry – it is clearly more likely that prosecutions will be brought in respect of counterfeit drugs than pirated DVDs. Indeed, in the case of a risk which may have serious consequences such as death or infirmity, it may be possible to impose aggravated penalties.

Other penalties are provided for, including a fine of up to €300,000, destruction of infringing goods and goods principally used in the manufacture of the goods in question; total or partial closure, on either a permanent or a temporary basis, of the establishment or shop primarily used to commit the infringement. Provision is also made for a permanent or temporary ban on engaging in commercial activities, placement under judicial supervision or judicial winding-up, and a ban on access to public assistance or subsidies. Finally, the publication of judicial decisions is provided for.

Crucially, the infringement must be intentional, that is to say that the act must be deliberate, whether it is an actual infringement, or an attempt at infringement, or aiding and abetting or inciting such an offence. This does not affect specific liability systems such as the system laid down for internet service providers in Articles 12 to 15 of the eCommerce Directive.^{vii} This exclusion could be crucial in the case of service providers that are simply hosting online pharmacies.

UK policy

If the draft Directive is approved, it will mark the first time that a criminal law has been introduced in Britain that has not come from Parliament and that Parliament will have no power to block. The Commission presented the legislation using powers granted to it by a controversial ruling of the European Court of Justice in September last year, which was made despite the opposition of 11 states, including Britain.

The European Court of Justice ruled that the EU had the right to require member states to introduce criminal laws because it was necessary to uphold EU legislation on combating pollution.^{viii} The Commission has insisted that the principle applies across all policies.

Under EU law, the anti-piracy legislation will be decided by qualified majority voting, meaning that if Britain is outvoted it will have to introduce the penalties into national law, even if it opposes them. In response to the European Court of Justices' ruling last year, some EU national government officials said that the issue was so sensitive that EU lawmaking would grind to a halt and member governments would refuse to pass legislation rather



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than accept harmonisation of criminal law.

Implications for the pharmaceutical industry

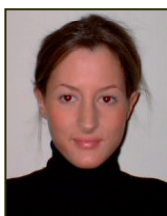
Prevention is arguably better than punishment and, increasingly, companies are joining together in industry or regional coalitions to deal with the counterfeiting crisis. One of the busiest groups, of which many drugs companies are already members, is the Quality Brands Protection Committee. Operating in China, it collects data on the scale of counterfeiting, and lobbies the government for better protection. It also educates police and customs officers on effective enforcement. Pharmaceutical companies may do well to build on this initiative to act together to combat counterfeiting in Europe.

One approach that companies take is to build anti-counterfeiting features into their products. Some of these, borrowed from pioneering security devices developed for use on paper money, are clearly visible and are intended to help consumers distinguish fakes from genuine goods. Many devices though, such as holograms, are themselves prone to counterfeiting.

Companies also use covert features, primarily to help them trace their products through the supply chain and to distinguish genuine articles from fakes, especially should they need to take the copycats to court. Molecular tags (such as DNA) are being used in products or on packaging to mark them in such a way that special assays can distinguish the real thing.

However, while detection and new technologies will help to fight counterfeiting, education, anti-corruption measures and enforcement are all critical in the war on fakes. While pharmaceutical companies may not be able to take action on all these fronts, it seems the EU intends to give a helping hand on enforcement.

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Notes

- i Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Health, World Health Organisation, April 2006, p.124.
- ii *Ibid*, p.124.
- iii http://europa.eu.int/comm/taxation_customs/customs/customs_controls/counterfeit_piracy/statistics/index_en.htm.
- iv *Ibid*.
- v <http://www.who.int/mediacentre/factsheets/fs275/en/>.
- vi Commission press release IP/06/532, 26 April 2006.
- vii Directive 2000/13/EC.
- viii Case C-176/03.