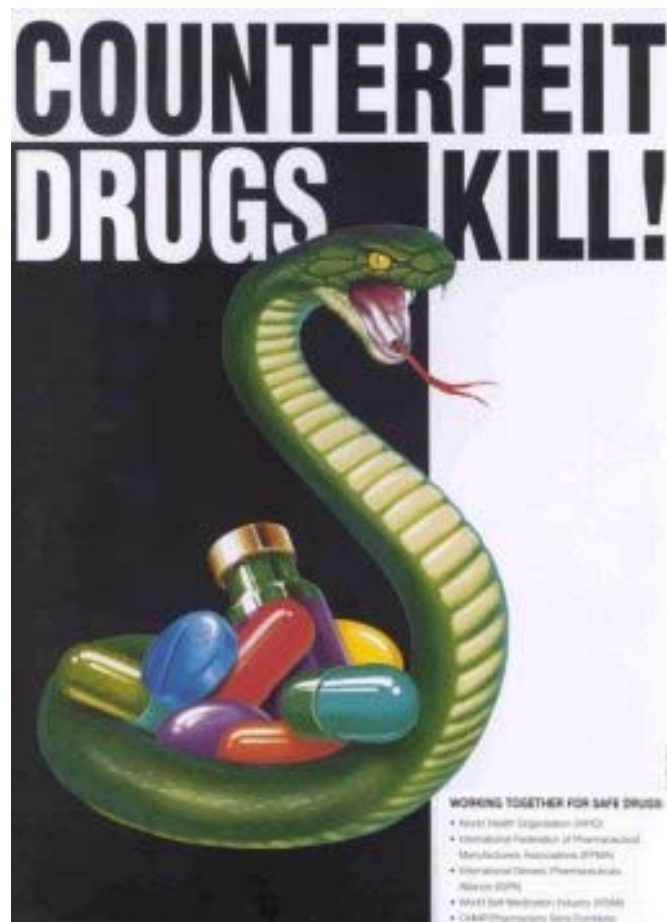


Counterfeit Drugs: Towards an Irish Response to a Global Crisis

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We live in a highly interconnected world, where information is flashed globally in nanoseconds. Such information can be harmless or deadly.

One emerging market is the sale of prescription medicines without either the intervention or assessment of Pharmacist or Doctor. This development raises concerns.

The issues surrounding this electronic market are many; foremost among them being patient or public safety, and also the important loss of revenue to the Pharmaceutical Industry. These losses may affect investment in new frontier medicines needed to treat the conditions for which current medications are not sufficiently effective or safe.

With this report prepared by Dublin City University researchers from the School of Nursing and the School of Law & Government, the Irish Patients' Association has sought informed direction for public awareness programs, and a seamless approach by government agencies to combat this problem nationally and internationally.

This report will be a contribution to the strategy required to protect patients, the public and other stakeholders.

I would like to sincerely thank the team at Dublin City University, through the project leader Dr Dónal O'Mathúna, and Minister of State at the Department of Health and Children, Mr Tim O'Malley for his support in enabling this report to be prepared.

Stephen McMahon

Chairman, Irish Patients' Association



Irish Patients' Association

Executive Summary

Ireland has benefited greatly from authentic pharmaceuticals. They contribute to both individual's health and the economy. Counterfeit drugs can seriously undermine both areas. Counterfeit drugs cause much death and suffering around the world. Different strategies are used to sell counterfeit drugs in developed and developing countries. Either way, they provide substantial incomes to unscrupulous individuals and organizations. The problem is global. It requires a coordinated global response.

Counterfeit drugs are defined in different ways. This creates difficulties in evaluating and policing trade in counterfeit drugs. A global definition needs to be accepted so that the problem can be tackled efficiently and globally. An important step towards this is on the horizon through the International Framework Convention on counterfeit drugs being developed by the WHO.

Tackling counterfeit drugs requires many different strategies involving the active cooperation of all stakeholders. These include governments, the pharmaceutical industry, healthcare professionals, police, customs, distributors, patients' organizations, and those concerned about people's rights. Most importantly they involve individuals making decisions not to purchase unregulated drugs of any kind, no matter how attractive they may seem. Only through individual decisions and global policies can society embark upon the elimination of this scourge.

Specific Recommendations

The rationale and justification for each of these is elaborated upon in this report. The recommendations are not listed in any particular order of priority.

- ✓ Ireland should encourage and actively engage with the development of an International Framework Convention on counterfeit drugs through the WHO.
- ✓ Laws that specifically address counterfeit drugs should be passed, putting civil and criminal sanctions in place for those who engage with counterfeit drug trade.
- ✓ All government departments with an interest in any aspect of counterfeit drug trade should cooperate in responding to this issue both locally and globally.
- ✓ Public health authorities should develop clear and efficient mechanisms that allow healthcare professionals and the public to report suspected counterfeit drugs.
- ✓ A media campaign is needed to bring accurate information on counterfeit drugs to the public's attention. Consultation with media experts is needed to ensure the most effective campaign is launched in a variety of outlets.
- ✓ Pharmaceutical companies should openly report cases of counterfeit drugs and cooperate with anti-counterfeit police and customs operations.
- ✓ Intensive international discussions are needed to find ways to reduce the cost of authentic pharmaceuticals in the developing world.

- ✓ Healthcare professionals should educate themselves on counterfeit drugs and ensure these issues are discussed in training programmes for future professionals.
- ✓ Healthcare professionals should be vigilant in checking for counterfeit drugs and alert patients to the dangers with counterfeit drugs.
- ✓ An Garda Síochána and Customs and Excise should be resourced to work with Interpol on counterfeit drug investigations.
- ✓ Research projects should investigate whether and to what extent An Post and other package carriers are being used to bring counterfeit drugs into Ireland.
- ✓ Research projects should be funded into the development of portable and inexpensive testing kits to permit rapid identification of authentic and counterfeit drugs.
- ✓ Research projects should be funded and conducted to describe the extent of the counterfeit drugs problem in Ireland.
- ✓ Research should be funded and conducted into the extent to which Irish people use the Internet to obtain all forms of medicinal products.
- ✓ Research should evaluate the quality of all types of medicinal products available in Ireland over the Internet.

Counterfeit Drugs: Towards an Irish Response to a Global Crisis

Background

The counterfeit drug problem gives Ireland a unique opportunity to make a significant contribution to global health. One estimate from the World Health Organization (WHO 2005) claims that 60 percent of counterfeit drugs impact developing countries. Ireland has a long tradition of helping the poor and vulnerable in those countries. Taking the initiative to address counterfeit drugs builds upon that tradition.

At the same time, Ireland has benefited greatly from the presence of the legitimate pharmaceutical industry. Ireland is one of the world's largest exporters of pharmaceuticals with €34 billion in intermediate and finished pharmaceuticals exported in 2002 (IDA 2005). Among the world's top selling drugs, 6 out of 10 and 12 out of 25 are produced in Ireland. These include Lipitor and Viagra, two of the widely counterfeited drugs. The potential impact of counterfeit drugs on the Irish economy is thus substantial. The presence of these pharmaceutical companies in Ireland provides a unique opportunity to facilitate discussions to develop strategies to tackle this problem effectively. In its concept paper on this issue, the WHO highlighted the measures taken by the United States, Nigeria, India, the Philippines and China (Forzley 2005). No European country was listed, providing Ireland with an opportunity to actively promote European involvement.

A perception exists that counterfeit drugs are only a problem for developing countries. Historically this may have been the case, but the impact is increasingly being felt in developed countries. Great difficulty exists in measuring the extent of counterfeit drugs in developed countries, including within Ireland. Recently, two incidents of illegal trading in counterfeit drugs worth €15 million were discovered in Switzerland (Pitts 2005). In the first incident, a Swiss wholesaler introduced counterfeit drugs into the German market. In the second incident, Swiss customs authorities stopped a large shipment of AIDS medicine from Africa intended for the E.U. market.

These cases highlight a much more sinister side to the counterfeit industry. The global problem of counterfeit products like films, software, clothes and CDs have been seen by some as 'victimless crimes'. Large corporations lose some profit, but the ordinary person in the street can better afford a counterfeit item than the authentic one. The claim is that no one really gets hurt.

Reality is very different. It is increasingly apparent that counterfeit products are part of the income generating and laundering sides of organizations devoted to crime and terrorism. Ireland was represented at meetings organised by Interpol in which counterfeit products, including drugs, were reported to account 'for much of the money the international terrorist network depends on to feed its operations' (Millar 2002).

But the harm from counterfeit drugs is even greater. A counterfeit CD or T-shirt will not cause direct harm to the purchaser. The direct harm to those purchasing counterfeit drugs is of the most serious kind. Little wonder headlines introduce the issue with terms like 'Murder by fake drugs' (Newton et al 2002). The issue needs urgent attention.

The Problem

Counterfeit products have been a problem throughout human history. Counterfeit drugs are not new. A product said to be made from the horn of the legendary unicorn was sold for centuries to treat fevers or poisonings and to restore strength. Its popularity did not wane until it was shown to be made from the horn-like teeth of a whale species (Shepherd 1930). All that has changed is the extent of the problem, and its devastating consequences.

Assessing the extent of the problem

It is difficult to assess the extent of counterfeit drugs in the world. There are four reasons for this. First, like corruption, every person involved in counterfeit drugs commits an illegal act. There is no incentive for any individual to report the illegal act. Second, States commit limited or no resources whatsoever to detect counterfeit drugs. More than half of the States of the world have no drug regulatory or consumer product safety authority (Forzley 2005 p14). Third, States have yet to agree on a universal definition as to what constitutes a counterfeit drug. Fourth, the method of distribution varies from State to State and between the developing and developed world. For example, many counterfeit drugs are distributed in the developing world via local markets whereas in the developed world they are distributed via the Internet.

Therefore, it is not surprising to discover that estimates range widely as to the extent of the problem. A spokesman for the U.S. Food and Drug Administration (FDA) claimed that up to 15 percent of the drugs sold in the world are counterfeit (Cockburn et al 2005). This number jumps to 50 percent in parts of Africa and Asia (Gibson 2004a). The WHO estimates that counterfeits make up between 5 and 8 percent of the \$550 billion in medicines sold each year. However, the WHO stated that this estimate was based on incomplete information and the actual amount could be higher (WHO 2005).

Human cost – public health and safety

The primary problem with counterfeit drugs is the significant danger they pose to public health and safety. In developing countries, people and organisations are using the few resources they have to purchase life-saving medications. Desperate people who can't afford the full price of a drug known to be effective grasp at the opportunity to get an affordable product. When they get a fake product, the consequences are often fatal. Many report the problem as one of wholesale murder. Some of the most vulnerable people in the world are being exploited because of their great need. This is a humanitarian crisis of huge proportions that deserves greater attention. A number of incidents reveal the danger that counterfeit drugs pose to people around the world.

A meningitis epidemic broke out in Niger in 1995. Nigeria donated 88,000 vaccines in good faith only to learn later that the products were counterfeit and contained no active product. It is estimated that 2500 people died because of these fake vaccines (ICN 2005). A 1999 survey in Cambodia found that 60 percent of the 133 drug vendors interviewed were selling as the antimalarial mefloquine tablets with cheap, ineffective drugs or no drug at all (Newton et al 2002). Hundreds of children have died in Haiti, Nigeria, Bangladesh, India and Argentina due to antifreeze (diethylene glycol) being used to give fake paracetamol syrup the right consistency (O'Brien et al

1998). Fears are mounting that counterfeit products being sold as antiretroviral drugs in central Africa may set back the treatment of AIDS in serious ways (Ahmad 2004).

The cost in lives and suffering is inestimable. Newton and colleagues (2002) summarised the situation in an editorial in *BMJ*: ‘The accumulated evidence, such as it is, suggests that mortality and morbidity arising from this murderous trade are considerable, especially in developing countries.’

Counterfeit drugs also pose a danger to public health and safety in developed countries, though the issues are somewhat different. There, many of the counterfeit drugs are not taken for life-threatening illnesses, but as lifestyle medicines. Drugs taken for erectile dysfunction, to control cholesterol levels and to enhance athletic performance make up the bulk of the illicit trade (Reuters 2005). However, the problem is growing. In the U.S., the FDA initiated 58 investigations into counterfeit drugs in 2004, compared to thirty in 2003 and six in 2000 (Reuters 2005).

In 1996 a pharmaceutical distributor admitted that it had for years imported counterfeit drugs into the U.S. from an unapproved source in China (CBS 2002). One of these imported drugs caused at least 66 deaths and hundreds of severe reactions. In 2000, Italian authorities seized 24,000 packs of medicines and 2 tonnes of raw materials worth \$1million (Farnsworth 2005). In 2002, Ohio police seized 36,000 bogus Viagra pills that were traced back to China (U.S. Army 2002). In 2004, fake bottles of Cialis, used to treat erectile dysfunction, were discovered in the U.K. (Gibson 2004b). Later that year, British authorities shut down a factory in London that was producing half a million Valium, Viagra and steroid tablets every day (Reuters 2005). In 2005, they seized thousands of fake Viagra pills made in India and later discovered packs of counterfeit Lipitor.

The convictions reported in November 2005 of a former Co. Clare physician and another man show that illegal trading in pharmaceutical drugs is also occurring in Ireland (Lucey 2005). Investigations into the extent of the problem in Ireland are needed.

This problem is not limited to ‘lifestyle’ drugs such as Viagra and steroids. In 1982, seven people in the U.S. died after using paracetamol tablets laced with cyanide (Cockburn et al 2005). In 2003, the U.S. was flooded with nearly 200,000 bottles of counterfeit Lipitor, a product widely used to control cholesterol levels (ICN 2005). Little is known about the extent of counterfeit drug use and availability in Ireland. Research is urgently needed to investigate the extent of the problem.

Financial and other costs

The money involved in counterfeit drugs is substantial. The FDA estimates that 10 percent of the market value of medicines globally is used on counterfeit drugs (Cockburn et al 2005). The global market in fake drugs is at least a US\$35 billion industry. There are also the incalculable financial costs to the reputation of the pharmaceutical companies and public health systems. Some damaging effects of counterfeit drugs are more long-term. One is a breakdown in trust. People will lose faith in the health system if they cannot trust the reliability of medicinal products. For example, effective vaccination programmes require that a high proportion of the population be vaccinated. Yet if the supply of vaccines becomes tainted with

counterfeit, ineffective vaccines, people's willingness to use them may be reduced. People in developed countries have been fortunate to have high-quality products, but such may not continue to be the case if the global problem of counterfeiting is not aggressively tackled.

Another long-term harm relates to drug resistance. Antibiotic resistance is a very significant problem for several reasons. Resistance is also developing to medications used to treat AIDS, malaria and other infections. Counterfeit antibiotics containing reduced amounts of antibiotics will deliver less than effective doses and contribute to the development of drug resistant strains. A study in Nigeria found that 35 of 49 types of antibiotics had fake versions (Stearn 2004). Fears were mounting that resistance was developing to the new antimalarial drug artesunate because it was increasingly reported as ineffective. However, the problem turned out to be the widespread (up to 38 percent of packs) introduction of counterfeit products containing no artesunate (Aldous 2005a).

Organised crime

It is not surprising to learn that some of the most notorious criminal and terrorist organisations are interested in counterfeit drugs. There are a number of reasons for this including:

- Counterfeit drugs are high value items in relation to their bulk/size
- The production of counterfeit drugs does not require an expensive infrastructure
- Licensed distributors, pharmacists or patients may be unable to detect or differentiate between counterfeit and genuine drugs
- Counterfeit drugs are relatively easy to hide and transport
- The Internet facilitates direct marketing of counterfeit drugs to 'consumers'
- The need and demand for pharmaceuticals is continuous.

Some people tackling the counterfeit drugs problem take the ultimate risks. Dora Akunyili, director-general of the Nigerian agency combating counterfeit drugs, has had death threats against her family and survived one assassination attempt (Aldous 2005b). The people and organisations fighting this issues 'in the trenches' need significant support from those with the resources and opportunities to assist.

Global Trade and the Internet

A number of reasons can be offered to suggest that Irish patients are being exposed to counterfeit drugs. Developed countries have become easier targets of counterfeit drugs due to the increased ease of global trading and travel. The elimination of trade barriers allows drugs manufactured in one State to arrive in another State without required inspections by customs. This facilitates the export and import of counterfeit drugs.

More people visit foreign countries where they can purchase prescription and other medicines, often at highly reduced prices. They may have no way to identify whether these are legitimate or counterfeit, nor might they be aware of the potential dangers from counterfeit drugs. Increased migration into Ireland opens up many opportunities for positive interactions with less developed countries, but may also open channels for

those seeking to sell counterfeit drugs. The extent to which counterfeit drugs are being brought to Ireland via these channels needs to be investigated.

Irish people, like those around the developed world, are increasingly using the Internet to seek information and make purchases. Although studies were not based in Ireland, various estimates find that between 36 and 55 percent of those using the Internet are seeking medical information (Schmidt and Ernst 2004). Accessing health information was one of the most common reasons why 29 million people in the U.K. use the Internet (Molassiotis and Xu 2004). Internet and email users are continually exposed to advertisements offering drugs and other medicinal products. Some of these offer prescription drugs at much reduced rates. They offer prescription drugs without the expense or inconvenience of having to obtain prescriptions. For example, one in five Websites selling prescription-only medicines did not require prescriptions (Bessell et al 2002). The Internet offers herbal remedies and dietary supplements that claim to be as effective as prescription drugs (the infamous Herbal Viagra). While all types of medicines are available, the identity and quality of many products are unknown. One survey found that only 12 percent of e-pharmacy Websites displayed any form of quality accreditation seal (Bessell et al 2002).

The extent to which people in Ireland use the Internet to purchase drugs and supplements is not known. Research is needed into this phenomenon to gain a clearer understanding of any problems.

Alternative therapies and the Internet

Many patients are more willing to use complementary and alternative medicine (CAM). There are significant risks associated with these therapies and remedies as many are not regulated by law. Forty-eight percent of Americans using the Internet for health purposes were seeking information on CAM. This has led to several studies of the quality of the information on these Websites (Schmidt and Ernst 2004). One study used the five most popular search engines to look for information on the eight best-selling herbs (Morris and Avorn 2003). The quality of the information was particularly poor on those Websites which also sold products or were directly linked to a seller, which constituted three-quarters of the sites.

More than three-quarters of these Websites made claims alleging that the herbs could improve health which they are not legally entitled to make according to U.S. law. Half made illegal claims about the products curing diseases. Many sites did not include well-known information about adverse effects. Only 12 percent of the Websites referenced any studies to support the claims they made. In other words, most of the popular U.S. Websites offering information on herbal remedies present inaccurate, incomplete, and unreferenced information that frequently violates their own law (Morris and Avorn 2003).

Another study examined herbal information related to cancer. Websites scored an average of 22 out of 50 on quality, which was poor. The average for safety was 13 out of 30, also poor. Non-commercial biomedical Websites had substantially higher quality information, but the researchers concluded that, "Commercial sites had the most inaccurate or misleading information, emphasizing only the positive aspects of the use of herbs, with little or no evidence" (Molassiotis and Xu 2004).

Use of the Internet to purchase supplements is promoting attitudes and approaches which play into the hands of those selling counterfeit drugs. People are seeking a greater role in making health-related decisions. Many want to make autonomous decisions or supplement the information they obtain from healthcare professionals. Yet in turning to the Internet they are exposed to many inaccurate and unsubstantiated claims. Ironically, in trying to take control of their health decisions, people may expose themselves to heightened dangers.

The quality of products available over the Internet is unknown. However, herbal remedies and dietary supplements sold in health food shops and pharmacies are frequently of sub-standard quality (Larimore and O'Mathúna 2003). If these are an indication of the quality of products available on the Internet, some would be classified as counterfeit drugs. For example, numerous cases of heavy metal toxicity have been associated with herbal remedies. Seventy Ayurvedic herbal remedies manufactured in India and Pakistan were purchased in the Boston area (Saper et al 2004). When examined for heavy metal content, twenty percent of the products were found to contain lead, mercury and/or arsenic. If taken according to recommendations given on the products, all of these would have resulted in heavy metal intakes above regulatory standards—some of them three times the recommended reference doses.

Herbal remedies have also been found to contain pharmaceutical drugs. A study in the Middle East of 247 herbal remedies found that over thirty percent were contaminated in some way (Bogusz et al 2002). Of these, eight contained pharmaceutical drugs. For example, Valium-like drugs were found in herbal sedatives and ibuprofen in herbal capsules for rheumatism.

Many of the same Websites promoting questionable products criticise the pharmaceutical industry and government regulatory agencies. Sixteen percent of CAM Websites actively discouraged people from using conventional medicine (Schmidt and Ernst 2004). While some criticism of current regulation may be warranted, the appropriate response is to reform and improve existing regulation, not call for its abandonment. Yet weak regulation is one of the features found by the WHO to lead to increased trade in counterfeit drugs (WHO 2003).

Studies have shown that people are uncritical in their assessment of information on the Internet (Morris and Avorn 2003). This raises concerns that need to be investigated further to give greater understanding of people's decision-making strategies regarding drugs and supplements. The increased use of the Internet for health information and purchase of health products puts people at increased risk of adverse effects and exposes them to unnecessary risk when they obtain ineffective or counterfeit products.

Different Approaches to Counterfeit Drugs

Counterfeit pharmaceuticals are put into circulation in at least three different stages. The first stage is sourcing the counterfeit drugs. These include genuine pharmaceuticals that have been stolen, expired pharmaceuticals, manufactured counterfeit products and contraband. The second stage involves the wholesale distribution of these counterfeit drugs that may or may not involve the packaging and repackaging of these drugs. These drugs may be distributed to governmental health systems, hospitals, pharmacies or other legitimate or illegitimate distributors. The

third stage is the distribution to the individual. This may occur through legitimate sources (many unaware of the products' source), through street markets in developing countries or over the Internet.

The World Health Organization carried out a study of counterfeit drugs between January 1999 and October 2000 (WHO 2005). During this time they collected 46 confidential reports from 20 countries. Sixty percent of these came from developing countries. This was not a rigorously controlled study, but it showed a wide range of counterfeited drugs, included antibiotics, hormones, analgesics, steroids, and antihistamines. The ways in which products were counterfeited can be grouped into six categories:

1. Products without active ingredients, 32.1%
2. Products with incorrect quantities of active ingredients, 20.2%
3. Products with wrong ingredients, 21.4%
4. Products with correct quantities of active ingredients but fake packaging, 15.6%
5. Copies of an original product, 1%
6. Products with high levels of impurities and contaminants, 8.5%

The range of practices shows the need for agreement on a definition of 'counterfeit'.

Legal Definitions

Counterfeiting is a form of deceit. A counterfeit product is something that has been forged, copied or illegally imitated for the purpose of extracting money from credulous or consenting clients to the detriment of the legal manufacturer. According to Black's Law Dictionary, a counterfeit product is one that is made by somebody other than the genuine manufacturer by copying or imitating an original product without authority or right with a view to deceive or defraud by passing the copy or forged product for that which is original. Ireland does not have a legal definition of counterfeit drugs.

A number of States have adopted different legal definitions for counterfeit drugs. The elements of these definitions include:

Misrepresenting the counterfeit drug as a genuine drug: In the United States, the federal Food, Drug and Cosmetic Act 2000 defines a counterfeit drug as a drug where the 'the container or labelling of which without authorization bears the trademark, trade name, other identifying mark, imprint, or device or any likeness thereof, of a drug manufacturer, processor, packer or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such drug in which thereby falsely purports or is falsely represented to be the product of, or to have been packed or distributed by such other drug manufacturer, processor, packer or distributor.' In the Philippines, the definition includes 'a drug deliberately and fraudulently mislabelled with respect to its source and or identity.' Similar definitions exist in the laws of Pakistan and Nigeria.

Importation, sale or distribution of an adulterated drug (U.S. federal law and in Burma)

A drug whose expiration date has been reached or is past (Burma)

A product with insufficient or no active ingredients (Philippines)

A product with wrong ingredients is a counterfeit drug (Philippines)

A product that has been manufactured with harmful substances (Burma)

The different focuses of these laws may reflect the different problems caused by counterfeit drugs in these States. The absence of a common universal legal definition has two significant consequences in dealing with counterfeit drugs. First, States find it difficult to exchange information about counterfeit drugs where they define counterfeit drugs differently. Second, it limits the ability to understand the true extent of the problem at a global level.

The World Health Organisation has suggested the following legal definition: ‘a counterfeit drug 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 the wrong ingredients without active ingredients with insufficient active ingredients or with fake packaging’ (WHO 2005).

Agreement on a definition is urgently needed. A draft Concept paper for an International Framework Convention has been circulated by the WHO (Forzley 2005). This will be discussed at a conference in February 2006 being organised by the WHO. Any resulting Framework Convention would include an agreed upon definition of counterfeit drug. The draft paper includes the above definition as a starting point. Ireland should support this important initiative and may have a unique role to play here because of the pharmaceutical industry based in the country.

Existing Legal Remedies to Combat Counterfeit Drugs

International conventions are an important aspect of combating counterfeit drugs. Until such a legal tool is in place, current legislation can be used to impact this illegitimate trade. Currently existing legal remedies to combat counterfeit drugs include:

Breach of intellectual property rights: A counterfeit drug may breach the intellectual property rights of the manufacturer of the genuine drug. This can involve a breach of patent, a breach of trademark or involve the tort of passing off. A pharmaceutical manufacturer can institute civil proceedings for breach of patent where the counterfeit drug has the same or similar ingredients to the genuine drug. A pharmaceutical manufacturer or licensee could institute civil proceedings for breach of trademark where the counterfeit drug bears the trademark of the genuine drug without the manufacturer or licensee’s consent. Gardaí and Customs and Excise may also initiate criminal proceedings for breach of trademark.

A pharmaceutical manufacturer could also sue for the tort of passing off where the counterfeit drug uses the same or similar name and product packaging as the genuine drug (*Smithkline Beecham plc v. Antigen Pharmaceuticals*, High Court, McCracken J., 25th March, 1999). Legal proceedings for breach of intellectual property rights present difficulties. A pharmaceutical manufacturer will initiate civil proceedings where the counterfeit drug is causing a significant loss in sales of the genuine drug or significant

damage to the reputation of the genuine drug. These may be difficult to establish. There are also practical difficulties in identifying and locating the party responsible for breach of the intellectual property rights, particularly where this is in a foreign State. This gives rise to jurisdictional issues.

Many fake pharmaceuticals are manufactured in developing States. The attitude of developing States to intellectual property rights has often been very negative. Intellectual property rights are considered to be responsible for the high cost of drugs and are seen to place foreign interests over domestic interests. However, membership of the World Trade Organisation requires States to enshrine these rights into law. Developments in this area will be needed to facilitate cooperation between States on several issues related to counterfeiting.

Breach of Irish and E.U. Regulation of Medicinal Products: In Ireland, there are regulations for the manufacture, distribution, advertising and sale of pharmaceutical drugs. The regulations call pharmaceutical drugs ‘medicinal products’. It is a criminal offence to breach these regulations. The Irish Medicines Board is the enforcement authority for these regulations. A counterfeit drug may breach these regulations in the following different ways:

- Importing, placing on the market or otherwise selling any medicinal product or procuring the manufacture for sale of any medicinal product without a licence granted by the Irish Medicines Board. [Medicinal Products (Licensing and Sale) Regulations 1998 (S.I. No. 142 of 1998) Regulation 3]
- Keeping, offering for sale, or selling by wholesale any medicinal product without a wholesale licence granted by the Irish Medicines Board. [Medical Preparations (Wholesale Licenses) Regulations 1993 (S.I. No. 39 of 1993) Regulation 4 and Medical Preparations (Wholesale Licenses) (Amendment) Regulations 1996. (S.I. No. 41 of 1996)]
- Supplying certain medicinal products without a prescription. [Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) Regulation 5]
- Certain medicinal products can be supplied without a prescription, but such products must be supplied in a pharmacy in accordance with the Pharmacy Acts, 1875 to 1977 and such supply must be effected or supervised by a pharmacist. [Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) Regulation 6]
- Failing to display required label information on a container or outer package of a dispensed medicinal product. [Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) Regulation 9]
- Failing to provide certain information on the packaging and/or on a leaflet of a medicinal product. [Medical Preparations (Labelling and Package Leaflets) Regulations 1993 (S.I. No. 71 of 1993) Regulations 3-9 as amended by Medical Preparations (Labelling and Package Leaflets) (Amendment) Regulations 1994 (S.I. No. 440 of 1994) and Medical Preparations (Labelling and Package Leaflets) (Amendment) Regulations 1999 (S.I. No. 187 of 1999)]

- Supplying of medicinal products for use as such after the expiry date of the medicinal product in question. [Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) Regulation 18]
- Supplying medicinal products by way of mail order. [Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) Regulation 19]
- Supplying certain homeopathic medicinal products and herbal substances in breach of the regulations. [Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) Regulation 19, Medicinal Products (Licensing and Sale) Regulations 1998 (S.I. No. 142 of 1998) Regulation 8, Medical Preparations (Licensing, Advertisement and Sale) Regulations, 1984 to 1994 and Medical Preparations (Labelling and Package Leaflets) Regulations, 1993 and 1994]
- Advertising through any medium a medical preparation that does not have a product authorisation or is a product that requires a prescription. [Medical Preparations (Advertising) Regulations 1993 (S.I. No. 76 of 1993) Regulations 4 and 5.]
- Placing dangerous products on the market. The safety of a product is determined by taking into account the characteristics of the product including its composition and packaging. [Medical Preparations (Advertisement and Sale) Regulations 1958 (S.I. No. 135 of 1958)]

The vast majority of these regulations have been issued in order to bring Irish law into conformity with EU laws. The purpose of these EU laws is to remove differences in Member States laws regulating medicinal products so that the internal market in pharmaceuticals may function more effectively. The safeguarding of human health from drugs genuine or otherwise is an indirect benefit of these EU laws. Directives 2004/27 and 2004/24 make changes to this regulatory system. However, the current regulatory system does not directly attack the difficulty of counterfeit drugs from a patient safety perspective.

Irish and European laws make many aspects of counterfeit drugs illegal. This is achieved indirectly because counterfeit drugs breach the licensing and regulatory system for legitimate drugs. There is a need to tackle counterfeiting head on with a range of civil and criminal sanctions for those who engage in a trade that poses a significant and ever-increasing threat to global health.

Jurisdictional issues concerning detection, prosecuting and evidential proof

The vast majority of counterfeit drugs appear to be manufactured in other States and imported into Ireland. Under international law, Ireland is entitled to proscribe that an activity occurring in another State is a criminal offence under that Irish law. Ireland can do this where the perpetrator (technically called the active national principle) or victim (technically, passive national principle) of the offence is an Irish citizen. However, Ireland would need the co-operation of the other State to prosecute the criminal offence. Ireland would need the State to investigate the offence and extradite the perpetrator to Ireland to stand trial. The foreign State may not be willing to offer

such assistance where it has weak laws controlling the manufacture, distribution and export of drugs and counterfeit drugs.

The only way of tackling this problem is through international co-operation. There is a need for an international anti-counterfeiting drugs treaty with deterrent penal sanctions and strong enforcement powers whose aim is the protection of human health. Such a treaty would make it a criminal offence to be involved in the manufacture, distribution, sale and advertising of counterfeit drugs. Such an offence should carry significant criminal sanctions to reflect the significant danger that counterfeit drugs pose to patients. This treaty should foster co-operation between different national law enforcement agencies, customs, police, prosecutors and legitimate pharmaceutical manufacturers. The establishment and harmonisation of criminal laws regulating counterfeit drugs would prevent criminals from finding States where they face little or no criminal sanctions for their behaviour. It would impose greater international licensing requirements for manufacture, wholesale and supply of medicinal products. There would also be powers of search and inspection of counterfeit drugs. There would be a system for rapid reporting of suspected counterfeit drugs. Pharmaceutical manufacturers would be encouraged to protect medicinal products from being imitated or copied and to ensure traceability of products.

The draft International Framework Convention on counterfeit drugs

A draft international framework convention will be discussed at the WHO conference planned for February 2006 in Rome (Forzley 2005). Adoption of such a convention would represent an important step towards effective combating of international trade in counterfeit drugs. Ireland should support and actively engage with this initiative to the fullest extent possible.

There are two reasons why an international framework convention on counterfeit drugs is an imperative. First, national measures are insufficient to meet all the challenges posed by counterfeit drugs (Forzley 2005 p14). Second, trade in counterfeit medicines is a global activity and thus has international dimensions (Forzley 2005 p16).

The proposed international framework convention would provide a universal definition as to what constitutes a counterfeit drug. The existence of different State definitions makes it harder to collect and compare data and to implement measures to combat counterfeit drugs (Forzley 2005 pp11-12). The international framework convention seeks to provide that there will be universal jurisdiction for the crime of counterfeit medicines (Forzley 2005 p19). This is important since universal jurisdiction allows any State to prosecute for the offence irrespective of where the offence is committed and the nationality of the offender.

There are other important aspects to the draft framework convention. These include:

- Applies to counterfeit drugs and bulk ingredients
- Protection of each aspect of the supply chain
- Education, training and public awareness
- Sanctions and offences
- Exchange of information and provision of technical support

- International co-operation between all parties
- Establishment of an international body with powers and responsibilities under the convention or giving such powers and responsibilities to an existing body such as the WHO
- Requirement for States to report to the international body on steps taken to implement the convention and provide information on serious incidents of counterfeit drugs

The draft international framework convention recognises that combating counterfeit drugs requires the participation of every stakeholder including governments, law enforcement agencies, health professionals, the pharmaceutical industry, importers, distributors, consumer organisations and patients. Neither one solution nor any one stakeholder is enough to effectively combat the problem (Forzley 2005 p15).

Recommendations for Various Stakeholders

The Irish government

The Irish government should act on this issue both locally and globally. Engagement with the WHO's efforts to develop an international framework convention has been describe. Ireland should encourage and assist other States, especially developing countries, in their efforts to improve their regulatory agencies. International cooperation will be needed for any response to be effective.

Within Ireland, all stakeholders will need to cooperate in a concerted manner. This can be encouraged and facilitated by the relevant departments within the Irish government. Funding will also be needed for some of the strategies and the research needed into various aspects of this issue. Some of this could come from the government through its research agencies, although other sources should be sought.

Most importantly, the Irish government can help draw attention to this problem and encourage the development of various strategies to tackle it.

Pharmaceutical companies

Any response to counterfeit drugs must involve the pharmaceutical companies. They have been engaging with the issue in different ways, including through the International Federation of Pharmaceutical Manufacturers and Associations. Such involvement should be encouraged. Yet some information on counterfeit drugs is kept secret by the pharmaceutical industry and governmental agencies. The Pharmaceutical Security Institute has a policy of not making public much information on counterfeit drugs (Cockburn et al 2005). Many pharmaceutical companies and organizations do not release information on counterfeit drugs. These policies sometimes lead to an unwillingness or slowness in alerting the public to the existence of counterfeit products. However, the Royal Pharmaceutical Society of Great Britain recently changed its position on this issue (Cockburn et al 2005).

Two reasons are usually given in support of secrecy. One is a business concern that if the public knows that counterfeit versions of a certain product are on the market that the reputation and sales of the product will be damaged. Some claim that rival companies will take advantage of their competitors' problems with counterfeits. The

second reason given is that news of counterfeit products could incite widespread public alarm, leading to an avoidance of necessary medications.

On the other side of the issue, though, is the harm from counterfeits to individual patients and healthcare systems. The widespread harm and death caused by counterfeit drugs must take a higher priority. Thus, the WHO has called for a reversal of these policies, and, if necessary, the compulsory reporting of incidences to relevant authorities (WHO 1999). Some companies have reversed their positions on this issue, leading to arrests and confiscations in some cases (Interpol 2005).

The argument for secrecy can be questioned itself. Counterfeit films and music do not diminish people's appreciation for the original performance. When people see the quality of some counterfeit products they may be more attracted to the higher quality of the authentic version. The same seems likely with counterfeit drugs.

Beyond that, the ethical mandate to protect people's well-being is a higher priority. Pharmaceutical companies have an opportunity to simultaneously promote global public health and protect their own interests. Effective strategies to combat counterfeit drugs will promote much public good. At the same time, they will remove products from the market that take away from the use of authentic products. An effective global strategy will require cooperation between all legitimate pharmaceutical companies and cannot be targeted at advantaging any particular products. The cooperation and public concern thus displayed will counteract the negative image sometimes portrayed that pharmaceutical companies are only concerned about profits. The long-term benefits to the pharmaceutical industry will far outweigh any short-term costs. The recent public alerts about counterfeit products released in the U.K. by pharmaceutical companies are a welcome example of a move in this direction (Cockburn et al 2005).

Pharmaceutical companies can also engage in ways to improve security techniques. A number of tracking devices are being tested with a goal of ensuring that an active ingredient or product can be traced. However, much work is needed on the effectiveness, safety and cost of these security measures. Investment is also needed into portable and inexpensive testing kits that will permit rapid identification of authentic and counterfeit drugs. Progress has been made in this area, but more work is needed (Aldhous 2005a).

Cost issues

Any discussion of a response to counterfeit drugs must address the difficult issue of medical costs. Counterfeit drugs are attractive everywhere because they are usually less expensive than authentic versions. Individuals and governments in some developing countries may never be able to afford authentic drugs. People in developed countries search the Internet and holiday sites looking for cheaper products.

There is no simple solution to the cost issues. Any solution will require open dialogue between all involved: pharmaceutical companies, governments, non-governmental agencies, healthcare professionals, patients and their representatives. One way to reduce the prevalence of counterfeit drugs is to reduce the cost of authentic drugs in the developing world. Developing States would also have to ensure that these lower-

priced drugs be given to their people, not used in corrupt ways to promote personal wealth. The extent of this problem, and the global harm and death it is causing, should provides an impetus to search for effective strategies to improve the situation.

Healthcare professionals

Healthcare professionals have a crucial role to play in this issue. The first step is to become educated themselves. Information should be presented within the training curricula for professionals, and in on-going education. Such information packages may need to be developed, and funding should be made available for this.

The International Council of Nurses (ICN) made counterfeit drugs the focus of International Nurses Day 2005. In conjunction with the International Federation of Pharmaceutical Manufacturers and Associations, it issued a report on the topic (ICN 2005). Such strategies are to be welcomed, and should be encouraged within all healthcare professions.

Healthcare professionals have an important role to play in alerting patients to counterfeit drugs and detecting their presence. The dangers of using drugs purchased from unregulated sources should be explained to patients. Doctors, nurses, pharmacists and others handling medications and evaluating patients should become familiar with the signs of counterfeit drugs. When patients do not respond as expected to medicines, counterfeit products should be explored as a possible explanation. Healthcare professionals should also see it as part of their ethical mandate to protect patients to report suspicion of counterfeit drugs to appropriate authorities.

Another way healthcare professionals can help respond to counterfeit drugs is by promoting evidence-based practice. Educators and professionals should frequently discuss the importance of high-quality evidence to support healthcare decisions. This ties into the broader issue of promoting a knowledge-based society. Antibiotic resistance is an important example. Inappropriate use of antibiotics arose for a number of reasons. One was public demand for antibiotics for inappropriate conditions; another was doctors' acquiescence to public demand. Education on the evidence for appropriate use of antibiotics, and the dangers of inappropriate use, was crucial to addressing the issue. The same approach is required with counterfeit drugs. Educators and professionals should stress the importance of using evidence-based decision-making strategies, not hearsay or unsupported promotions of products of unknown quality.

Public health authorities

Public health authorities must develop clear and efficient mechanisms to allow healthcare professionals and the public to report suspected counterfeit drugs. Response strategies need to be developed that coordinate all stakeholders and relevant authorities.

A media campaign is needed to bring this issue to the attention of the public. This campaign would need a number of elements to address the variety of issues raised in this report. This would require the engagement of a professional media communications company to develop an appropriate public campaign. An effective strategy would require information from some of the recommended research projects.

For example, information is needed about those groups of Irish people who most frequently use the Internet or holiday locations to purchase pharmaceuticals. Consultation would then be needed to identify how best to reach those groups of people. Information on the extent to which people in Ireland use the Internet to purchase medicines would also be helpful. Innovation ways should be explored to reach Internet users, and use of Internet sites and advertising should be investigated.

Any such public campaign will have to address the broader issues. The sense of control and autonomy that Internet purchasing brings will need to be addressed carefully. The greater public good of effective regulation must be emphasized. The harm to people from counterfeit drugs, and the widespread death caused in developing countries should be the focus.

Another broader issue requiring careful public attention is the way counterfeiting of certain products has become socially accepted among some. Copying certain products has been seen as a victimless crime or even a good that 'redistributes' wealth away from rich multinational corporations into the hands of ordinary people. Counterfeiting then becomes something acceptable for respectable citizens to do. Rejection of counterfeit drugs needs to be addressed within the context of rejecting all forms of counterfeit products. Any media campaign must highlight accurately the connection with organized crime and terrorism. It is crucial that this be based on clear evidence to avoid any appearance that the issue is being blown out of proportion to protect multinational corporations.

Any public campaign will need to involve several strategies, including public media advertising, public debates, and engagement with the media. Careful planning and consultation is essential to ensure effectiveness.

Police and customs authorities

Laws regarding counterfeit drugs will require enforcement. By its nature, counterfeiting is an international crime that requires global cooperation. In 2002, Interpol formed the Interpol Intellectual Property Crime Action Group to coordinate its response to counterfeiting of all types (Interpol 2005). The international police agency held discussions with many stakeholders, including the pharmaceutical industry. Arising from these, in partnership with the World Customs Organization, Operation Jupiter was launched at the end of 2004. This coordinated approach was piloted in South America over six months. It led to numerous arrests in three countries and the confiscation of counterfeit products worth around US\$4 (Interpol 2005). The operation was initiated in southeast Asia in 2005 and there are plans to start it in Africa (Reuters 2005).

Operation Jupiter provides a model by which an Garda Síochána and the Irish Customs and Excise could investigate counterfeit crime. The Gardaí should be facilitated and resourced to engage in this type of operation. Operation Jupiter in South America led to the arrest of two Taiwanese men with suspected links to organised crime. The impact of such operations could thus be much broader. One of the particular counterfeit operations unearthed by Operation Jupiter was originally identified by information from a pharmaceutical company (Interpol 2005). This demonstrates the importance and effectiveness of cooperation between all parties with a stake in this issue.

Postal services

In developed countries, much of the trade in counterfeit drugs occurs over the Internet. It can be assumed that Ireland falls into this category, although research is needed into the precise extent of this phenomenon. Such purchases require the involvement of postal services. An estimated 20 million packages of pharmaceuticals are imported by mail order into the U.S. annually, an increase of 1,000 percent in two years (Mortemore 2003). The FDA carried out a drug importation survey of mail facilities in 2003 and found that 88 percent of the packages contained unapproved drugs (Taylor 2003). Such a survey should be conducted in Ireland with a view to developing mechanisms by which importation of counterfeit drugs can be curtailed. Such a strategy will require coordination between An Post, other package carriers, the Gardaí and Customs and Excise.

Conclusion

Counterfeit drugs are a major problem. But they are part of an even larger problem. The search for cheaper medicines arises in part as a consequence of poverty and disparity between people around the world. Addressing the problem of counterfeit drugs has to be seen as part of a strategy to bring social justice around the world.

At the same time, greater resolve is needed to tackle the problem locally and globally. Only coordinated action will achieve success here. All stakeholders—governments, the pharmaceutical industry, healthcare professionals, police, customs, distributors, patients' organizations, and those concerned about people's rights—must unite against the scourge of counterfeit drugs. Many different strategies will be needed to combat this broad and serious problem.

The recommendations made here give Ireland the opportunity to lead the way in combating this global problem.

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