# Chapter 12

# PHARMACEUTICALS

## 12.1. General description

The purpose of this chapter[167] is to provide an overview of counterfeiting activities in the pharmaceuticals sector, assess the magnitude and trends of these activities, examine the effects on patients/consumers, companies and governments, as well as analyse the measures for combating counterfeiting and piracy activities.

The counterfeiting and piracy of pharmaceutical products involves the deliberate deception of patients, healthcare providers and suppliers of genuine products, such that they unknowingly acquire products of unverified quality, safety and efficacy. Thus, counterfeit pharmaceuticals very often infringe intellectual property rights, violate health and safety legislation and regulation, and create the potential for serious public health consequences.

Pharmaceuticals are understandably amongst the most heavily regulated products due to their direct impact on human health. Consequently, the counterfeiting and piracy of pharmaceutical products is, in most jurisdictions, subject to a myriad of laws and regulations, including those applicable to the regulation of pharmaceutical products, to intellectual property rights, in the criminal and penal field, to customs and border control, etc.[168] In addition to the applicable national legislation, from an international intellectual property perspective, the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) is also applicable. While this chapter will examine the issue of counterfeit and pirated pharmaceuticals primarily from an intellectual property perspective, it is important to highlight that the most harmful consequences of counterfeit pharmaceuticals are their nefarious implications for and impact on human health.[169]

167. This chapter was completed in mid-2007 and uses data and information mostly from 2004, 2005 and 2006. A more in-depth report covering exclusively the counterfeiting of pharmaceuticals will be published by the OECD in 2008 and will cover the latest data and information for 2007-08.

168. In fact, the same event may be viewed and counted from different perspectives. For example, the production of a counterfeit drug may constitute an intellectual property rights infringement, a regulatory violation and a criminal activity, and it may be pursued under any of these headings.

169. According to the World Health Organization (WHO), a counterfeit medicine is "a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products". IMPACT, "Counterfeit Medicines: An Update on Estimates", issued 15 November 2006.

**Table 12.1. Global pharmaceutical sales by geographic region (in USD), and by % of global sales**

| Pharmaceutical global sales<br>Total world market<br>Audited and unaudited data | 2001 | | 2002 | | 2003 | | 2004[1] | | 2005[2] | | 2006[3] | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | USD billion | % | USD billion | % | USD billion | % | USD billion | % | USD billion | % | USD billion | % |
| North America | 181.8 | 47.0 | 203.6 | 47.8 | 229.5 | 46.6 | 248 | 45.1 | 265.7 | 47.0 | 289.9 | 47.7 |
| European Union | 88.0 | 22.7 | 90.6 | 21.2 | 115.4 | 23.4 | 144 | 26.2 | 169.5 | 30.0 | 181.8 | 29.9 |
| Japan | 47.6 | 12.3 | 46.9 | 11.0 | 52.4 | 10.6 | 58 | 10.5 | 60.3 | 10.7 | 56.7 | 9.3 |
| Rest of Europe[4] | - | - | 11.3 | 2.7 | 14.3 | 2.9 | 9 | 1.6 | NA | NA | NA | NA |
| Asia, Africa & Australia | 27.9 | 7.2 | 31.6 | 7.4 | 37.3 | 7.6 | 40 | 7.3 | 46.4 | 8.2 | 52.0 | 8.6 |
| Latin America | 18.9 | 4.9 | 16.5 | 3.9 | 17.4 | 3.5 | 19 | 3.5 | 24.0 | 4.2 | 27.5 | 4.5 |
| Unaudited Countries | 22.8 | 5.9 | 25.4 | 6.0 | 26.7 | 5.4 | 32 | 5.8 | NA | NA | NA | NA |
| **Total** | **387** | **100%** | **426** | **100%** | **493** | **100%** | **550** | **100%** | **565.9** | **100%** | **607.9** | **100%** |

Notes:

1. Global pharmaceutical sales in 2004 are derived from IMS audits, which covers 95% of the market, the remaining 5% are estimates from IMS World Review. The 2004 numbers are missing data from Belarus, Bulgaria, Dominican Republic, Estonia, Lithuania, Russia and Ukraine as data was not available at time of analysis. Constant USD.

2. Excludes "unaudited data": information current as of 27 February 2006. NA = Not Available

3. Excludes "unaudited data": information current to 20 March 2007.

4. European countries not part of the European Union.

*Source*: IMS Health, 2007

The basic components of pharmaceutical products - active pharmaceutical ingredients (APIs) and excipients – have been the subject of counterfeiting activities. The finished pharmaceutical products – tablets, capsules, syrups, and injectibles – are commonly counterfeited. The packaging of pharmaceuticals has also been counterfeited and pirated.

Within the scope of this report, the term "pharmaceutical"[170] will be employed to include medicines requiring a prescription, medicines not requiring a prescription (*i.e.* over-the-counter products), vaccines, and herbal medicines/remedies where regulated. As well, the term "pharmaceutical(s)" will reference not only chemically-based products but also biologics. However, for the purpose of this chapter, this term will not cover medical devices or traditional medicines (*i.e.* homeopathic remedies), although it should be noted that counterfeiting and piracy has also expanded to these areas.[171]

Precise data on the size of the global pharmaceutical market are difficult to obtain, thus only a general picture is presented.[172] The audited and unaudited data for global pharmaceutical sales provides a general overview (IMS Health, 2007). The data demonstrate that the size of the global market, measured by sales, has increased annually and across all regions, having risen from USD 387 billion in 2001 to approximately USD 643 billion in 2006 (IMS Health, 2007). Specifically from 2005 to 2006, IMS reports that the global pharmaceutical market grew by 7%, to USD 643 billion.[173]

In 2005, the top 50 pharmaceutical companies accounted for USD 419.05 billion in global sales and spent USD 75.25 billion in research and development (R&D) (PharmaExec, 2006). The top 10 of the top 50 companies accounted for USD 249 billion in global sales and spent almost USD 45 billion on R&D. Amongst the top 50, the headquarters, on a per country basis, are predominantly situated in the United States (*i.e.* 20) and Japan (*i.e.* 12). In 2005, the top 10 selling products brought in sales of USD 56.9 billion, with Lipitor, the best selling pharmaceutical, bringing in USD 12.90 billion. In 2005, 13 products broke into the ranks of the blockbusters, bringing the number of products with total sales of more than USD 1 billion annually, up to 94 (Gray 2006). The top 10 therapeutic classes brought in sales of over USD 184 billion in 2005.

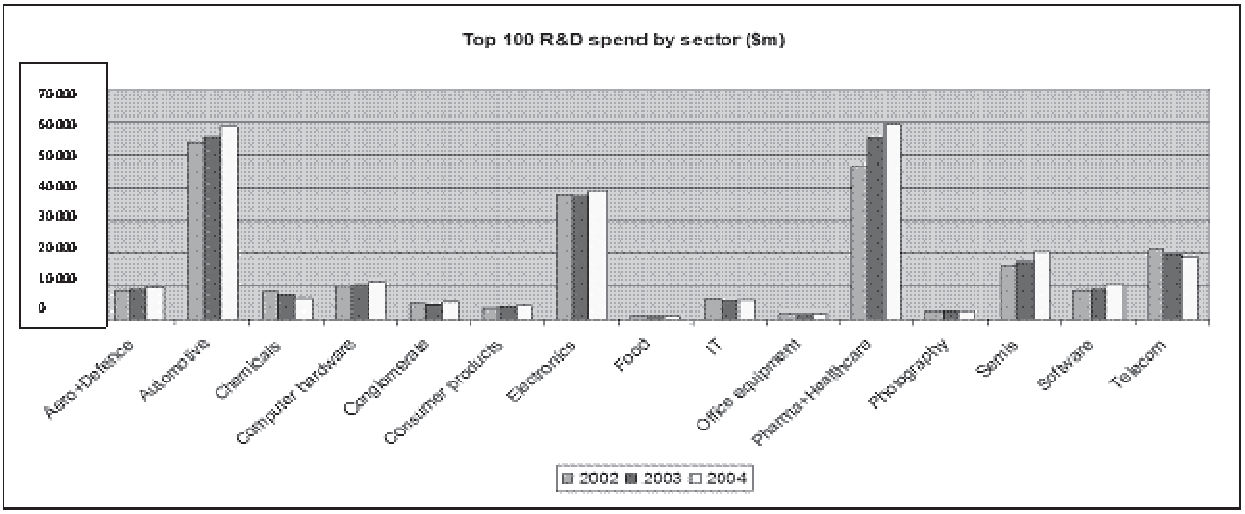
170. Within this paper, the terms "pharmaceutical product(s)", "pharmaceutical(s)", "medicine(s)", "drug(s)" will be used interchangeably.

171. As counterfeit medical devices and traditional medicines also raise health and safety concerns, they ought to be the subject of separate and detailed studies, and are beyond the scope of this report. The topics of parallel trade or re-importation are also beyond the scope of this chapter.

172. A more precise picture is not feasible due to a number of factors including the number and breadth of entities involved in this sector, including small, medium and large manufacturers (both brands and generics), wholesalers, distributors, retailers, pharmacies, and more recently, biopharmaceutical companies; the differences in statistical standards and definitions; the unavailability of data from privately-held entities; and the cycle of expansion and contraction of the sector. When these factors are multiplied across many jurisdictions, the information and data are difficult to collate and are disparate at best. The data and estimates provided are from various resources, including from public and private resources, media and filings with securities commissions.

173. The discrepancy between USD 643 billion used in the text and USD 607.9 billion reported in Table 12.1 is due to *1)* USD 643 billion includes unaudited data and *2)* variation in availability of information.

**Figure 12.1. Top 100 R&D spending**




*Source:* Cientifica[174], 2005.

The R&D of new pharmaceutical products is a lengthy (estimates vary, with average considered as 10 to 15 years), costly and complex process (OECD, 2006). One contributing element is the investment required for obtaining regulatory approval. For example, in the United States, only .01% to .02% of the compounds tested (*i.e.* 1 out of 5 000 to 10 000) receives regulatory approval (PhRMA, 2007). As Figure 12.1 illustrates, the pharmaceutical sector is one of the most research intensive (Cientifica, 2005). Based on a survey of 100 global corporations in a variety of fields, in 2004 the top two spenders in R&D by sector were pharmaceuticals and healthcare, at USD 59.33 billion[175], and automotive, with USD 58.83 billion. As seen above, in 2005, the top 50 companies spent USD 75.25 billion on R&D. R&D intensity charted by sector reveals software as the leader for 2004 at 18.2%, followed by pharmaceuticals at 12.5% (Cientifica, 2005). As such, this sector uses intellectual property, especially patents, trade secrets/know-how, trademarks, and copyright and design rights, to protect its investment in R&D.

## 12.2. Types of infringements

While the counterfeiting of pharmaceuticals violates health and safety legislation and regulation, it also involves the infringement of intellectual property rights through the intentional and deceptive falsification of one or more different aspects, including the bulk ingredients, the finished pharmaceutical product and the packaging. Counterfeit pharmaceuticals also compromise legitimate production/manufacturing activities, shipment and distribution/supply chains.

174. Cientifica carried out a global analysis of 100 corporate spenders on research and development over the last three years. Data was obtained from annual reports and encompasses corporations from Merck KGAA (USD 732 million spent in 2004), to Microsoft (USD 7 779 million spent in 2004).

175. The discrepancy between the figures presented by Cientifica and those above (based on the Pharmaexec.com study) are due to differences in the companies surveyed and the period covered by the surveys.

Numerous acts constitute patent rights[176] violation, including unauthorised production, use (including theft), offering for sale, sale or importing of the patented active ingredient, irrespective of the quantity of the active ingredient that is actually employed within the counterfeit pharmaceutical product. Moreover, patent rights are also infringed when a patented process or method is employed by the counterfeiters, as unauthorised users, to produce the active ingredient(s), excipient(s) or finished product(s).

The "name" or logo employed for sale of a product, the colour and shape of the tablets and pills, the packaging of the product, and any distinguishing feature may be the subject of a trademark. Under the new *Treaty on the Law of Trademarks*[177], which is awaiting ratification, rights holders will also be able to protect new types of marks, such as hologram(s), motion, colours, and marks consisting of non-visible signs, such as sound or taste. Counterfeiters pirate the logos, packaging, label, including holograms, shape, size and colour of the product in order to deliberately deceive the consumer into believing that they are acquiring the genuine product. In certain cases, the trademark for a given pharmaceutical product may become quite a valuable asset. For example, many (whether they use the product or not) are familiar with the trademark "Viagra", its distinctive blue colour and the lozenge shape of the tablet. Highly valuable trademarks may create additional incentive for counterfeiters. By using the rights holder's trademark, the counterfeiter is able to usurp the goodwill and product integrity associated with the valuable trademark, without the necessary investment or safeguards.

Copyrights are applicable to the packaging, the labelling, as well as the product information, instructions and inserts of pharmaceutical products. As such, when counterfeiters make or use unauthorised copies of such proprietary information, they engage in copyright infringing activities. Furthermore, use of packaging or labelling, which is inaccurate or misleading, will often also violate health and safety regulations.

Proprietors may also register the colour of the tablets or pills, as well as their unique shape, pursuant to industrial designs. Design rights are also applicable to the shape of vials or receptacles for the pharmaceuticals products. In jurisdictions where a product and its features may be protected by multiple intellectual property rights, IP holders may pursue counterfeiting and piracy activities on a multitude of bases.

## 12.3. Products most affected

### *12.3.1. Bulk ingredients*

The most important component of a pharmaceutical product is the Active Pharmaceutical Ingredient(s) (API). APIs are produced or purchased in bulk by manufacturers for use in the manufacturing of finished pharmaceuticals. The difficulties in detecting counterfeited bulk API lies in part in the difficulties that some authorities face due to lack

176. Pursuant to Article 28(1) of the TRIPS Agreement, "a patent shall confer on its owner the following exclusive rights: *(a)* where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; *(b)* where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

177. *Treaty on the Law of Trademarks*, ('Singapore Treaty'), adopted 27 March 2006, www.wipo.int/wipo_magazine/en/2006/03/article_0002.html.
While this treaty was adopted it was not in effect on 1 August 2007.

of capacity and technology. For example, one company reports an increase in the existence of counterfeit APIs and increased difficulties in distinguishing between the genuine and the counterfeit (OECD Survey, 2005). As many bulk ingredients are imported from foreign jurisdictions, there is considerable difficulty for the regulatory authority of one country to control and detect counterfeit APIs entering its borders. For example, one company detected in 33 countries counterfeit APIs sourced in India (OECD Survey, 2005). For example, in a 2000 testimony, the US FDA indicated that it was unable to detect or control all imported counterfeit bulk drugs from entering the United States, since there were, in 2000, over 1 200 foreign bulk drug producers (GlobalOptions, 2003). Pharmaceutical products also contain inactive, but important ingredients, known as excipients, which play an important role in the therapeutic performance and shelf life of both solid and liquid dosage forms.[178]

The intellectual property rights most often implicated in counterfeit bulk ingredients are patent and trademark rights. When the genuine API is protected by trademarks, counterfeiting activities constitute infringement of those rights. Bulk ingredients may be pirated through mislabelling or misbranding. To the extent that an API is protected by patents, the unauthorised use, production or adulteration of the API constitutes patent infringement. Counterfeit APIs may infringe not only product patents but also process and method claims, if the counterfeit is produced through processes and methods that are the subject of patent protection. However, since the detection of process and method infringement is more difficult than product patent violation, these types of violation are invoked less often. While the counterfeiting of excipients is less significant, the violation of intellectual property rights for excipients follows the pattern for APIs.

In addition to intellectual property issues, the counterfeiting of bulk ingredients raises health and safety concerns. Bulk ingredients are often manufactured in unapproved factories and under conditions not consistent with applicable health and safety regulations. For example, the counterfeiter may choose to mislabel an impure or inactive chemical as an API; to substitute the correct API with a lower or higher potency/dosage; to substitute the intended, often more-costly API with a cheaper one; or to re-label an expired API with a new and false expiration date (GlobalOptions, 2003).

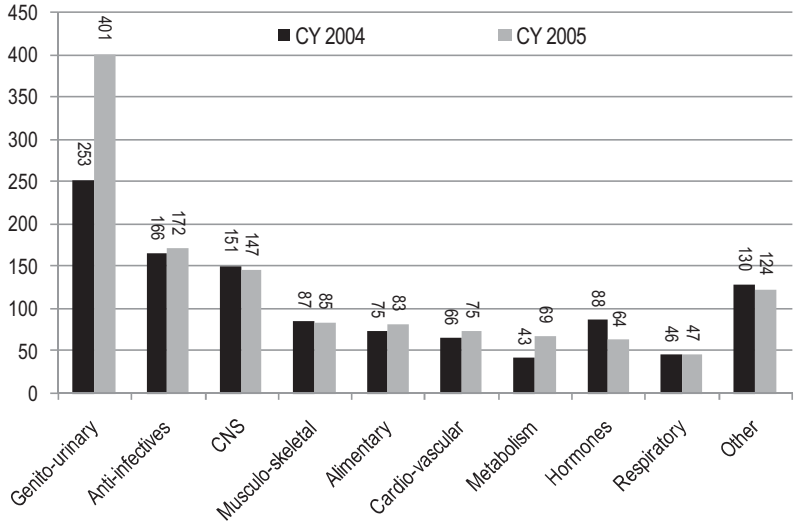
### *12.3.2. Finished pharmaceutical products*

Different data sources illustrate that finished pharmaceutical products covering a spectrum of therapeutic classes are being counterfeited. Examination of data for the European Union and North America shows that counterfeiters have targeted a wide range of modern drugs, including steroids, cancer (*e.g.* anti-tumour and anemia), erectile dysfunction, cardiology (cholesterol-lowering and hypertension), and hormones. By contrast, the most commonly counterfeited drugs in developing countries are the basic medicines against infection (antibiotics, anti-malarials, anti-retrovirals and anti-tuberculosis), analgesics, anti-inflammatory and anti-histamines and vitamins.[179] Figure 12.2 provides a limited global perspective on the frequency by which each therapeutic category is linked to counterfeiting, diversion and theft incidents.

178. According to the International Pharmaceutical Excipients Council (IPEC Americas, FAQs), excipients can be classified into the following functions: binders, disintegrants, fillers (diluents), lubricants, glidents (flow enhancers), compression aids, colours, sweeteners, preservatives, suspensing/dispensing agents, film formers/coatings, flavours and printing inks.

179. The data analysed represent a snapshot in time based on only 31 countries, including both developed and developing nations.

**Figure 12.2. Incidents by therapeutic category**




Note: "Other" includes: blood agents, cytostatics, dermatologicals, hospital solutions, parasitological & sensory organs.
*Source*: PSI Situation Report, 2005.[180]

The types of intellectual property rights most implicated in counterfeit finished pharmaceutical products include patents, trademarks and industrial design. The infringement of patent rights occurs when there is the unauthorised production, use, sale, importation of a patented active ingredient or excipient, or use of a process or method. An example is when the counterfeit pharmaceutical contains some active ingredient but the manufacturer is not an authorised licensee, such as the production of counterfeit "Levitra" in China (OECD Survey, 2005). The infringement of trademarks occurs when, for example, the counterfeiter is passing off the counterfeit as the genuine pharmaceutical product. Given that "passing off"[181] lies at the very heart of counterfeiting activities, trademarks, by their very nature, are the most easily and most frequently infringed IPRs. In other words, trademark infringement will arise even when there is no patent infringement; for example, a trademark violation may occur -- even when there is no use of a patented active ingredient, process or method -- as long as the counterfeit product uses an identical or confusingly similar trademark and is made to look and pass-off as the genuine product. For example, every counterfeit "Viagra", "Cialis", "Levitra", etc., tablet placed on the market in Europe violates the respective trademark. Industrial design rights are infringed any time the counterfeiter has copied the design of the genuine pharmaceutical, which has been registered in the applicable jurisdiction. Recently, more and more companies have begun to register the shape and design of particular pharmaceutical products. For example, for "Cialis", the shape of the tablet, the stamped lettering on each different dosage tablet (*i.e.* C10, C20), and the "C", have all individually been registered

180. The number of reported cases of counterfeit pharmaceuticals cited is very small compared with the true number of counterfeit drugs produced in this timeframe; and it is not possible to indicate with exactness to what extent the cases are representative of the drug categories involved, or the type of counterfeiting committed.

181. Article 16 of the TRIPS Agreement states that: "The owner of a registered trademark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs for goods and services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In the case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed."

in Europe under the Community Design.[182] Thus, every counterfeit "Cialis" tablet is violating these design rights.

A recent and worrisome occurrence, which may foreshadow the emergence of a new trend, is illustrated by the case of "Rimonabant"[183], a drug to treat obesity. It was advertised for sale over the Internet in March 2006, prior to its having received marketing authorisation by the European Commission (EU, 2006). In this case, the violation of intellectual property rights occurred prior to the rights holders having even placed the genuine product on the market, prior to their having begun to recoup on their investment, and even prior to the product having been declared safe for patient use. This example of the launch of a counterfeit prior to the actual marketing authorisation for the genuine product clearly represents a violation of health and safety regulations.

### *12.3.3. Packaging and labelling*

Counterfeit packaging and labels raise violations of copyright, trademark and design rights. Counterfeiters achieve their deceptive goal of passing off their products as the genuine item because they are able to copy the packaging and labelling of genuine products, re-date expired genuine products, or package counterfeit products in genuine packaging obtained through unauthorised means. One study examined 286 incidents and found that 67% had both counterfeit pharmaceutical and packaging, 28% had only counterfeit pharmaceutical and 5% had only counterfeit packaging (PSI, 2005). Counterfeiters employ state-of-the-art technologies to produce counterfeit labels that, on their face, are indistinguishable from the genuine original labels and apply them to the counterfeit bulk ingredients or finished pharmaceuticals. They have the ability to make and stamp tablets with company logos and even to package them in blister packs.

For example, in one seizure presses and punches that were used by counterfeiters to emboss the terms "Pfizer", "VGR 100" and "VGR 50" were seized (Pfizer, 2005). Investigations have highlighted that counterfeiters are able to reproduce tube vials and holograms, violating design rights. For example, very sophisticated holograms to protect genuine artesunate, an anti-malarial, have been copied by counterfeiters in Southeast Asia (Newton, 2006). They are often able to replicate them sufficiently well to deceive the average patient and possibly even the unaware medical professional. The presence of sophisticated holograms on the counterfeit product, even when the genuine packaging does not contain holograms, has been reported to increase consumer's acceptance of the counterfeit as genuine (Collier, 2005).

Another counterfeiting practice is to prolong the original and approved shelf life by replacing the date label, or repackaging the drugs with altered-date labelling. In this case, the pharmaceuticals have been obtained at low cost due to their being very close to, or having passed their approved expiration date. Such a drug is still a counterfeit, despite being produced by an authorised manufacturer through an approved process with the approved quantities of active ingredients under appropriate quality conditions. This situation raises a multitude of intellectual property, as well as health and safety violations.

182. For trademark information, see *e.g.* the Community Trademark database: http://oami.europa.eu/CTMOnline/RequestManager/en_DetailCTM_NoReg. For design information, see *e.g.* the Community Design database: http://oami.europa.eu/RCDOnline/RequestManager.

183. Developed by Sanofi Aventis. EU Commission, "Commission warns about fake drugs on the Internet", press release, Brussels, IP/06/375, 27 March 2006.

**Figure 12.3. Examples of counterfeit pharmaceuticals packing and labelling[184]**

(Top = original; Bottom = fake)

*Source:* Instituto Nacional de Medicamentos – ANMAT, 2006.

184. Colour pictures which better illustrate the differences between the original and the counterfeit packaging are available at www.oecd.org/sti/counterfeiting.

## 12.4. Magnitude, scope and trends

Counterfeiting of pharmaceuticals is an opportunistic activity which violates intellectual property, health and safety and criminal laws, amongst others, places patients' health at risk and whose detection and prevention is difficult. Assessing the prevalence of counterfeiting activities, both on a global and regional scale, is a difficult objective given the paucity of reliable data. The underlying reasons for such paucity include use of divergent definitions and terminology across jurisdictions, uneven or no data collection either within or across jurisdictions, differences in measurement techniques, variety of legislative and regulatory mechanisms pursuant to which investigations and prosecutions are carried out, a multitude of enforcement agencies involved in anti-counterfeiting activities, and the clandestine nature of such activities. Nevertheless, the available data suggest a rise in pharmaceutical counterfeiting, both in terms of volume and diversity of products affected. The analysis below aims to provide an overview, rather than a precise evaluation, and is based on OECD survey work and additional research.

Today, few jurisdictions, whether developed or developing, are immune from counterfeit pharmaceuticals and the infringement of intellectual property rights, as such activities have been reported on all continents (OECD Survey, 2005)[185]. A figure providing a global magnitude is not representative, since reports by region indicate a wide level of divergence. For example, the magnitude of counterfeit pharmaceuticals has been reported as low (*i.e.* less than 1%) for jurisdictions such as Australia, Canada, the EU, Japan, New Zealand and the U.S., versus 10% to 30% for some developing countries.[186] Jurisdictions are often the victims of multiple acts including production, sale, importation and export of counterfeit pharmaceuticals. For example, one entity reported that counterfeits of its pharmaceutical products sourced in China were detected in 42 countries (OECD Survey, 2005). Similarly, counterfeit active pharmaceutical ingredients have been reported as exported from India to 33 jurisdictions (OECD Survey, 2005). Data systematically collected by one entity provides some insight into the scope and magnitude of counterfeiting activities in different jurisdictions[187] (PSI, 2005, 2006).

185. With the exception, at the current time, of the two Poles.

186. WHO (2006*a*). "Counterfeit Medicines", Fact Sheet No. 275, revised November 2006.

187. It should be noted that the number of reported incidents and seizures in a specific jurisdiction is not necessarily indicative of the full scope of the counterfeiting and piracy problem in that jurisdiction, or the relative magnitude of pharmaceutical counterfeiting in one country vis-à-vis other countries worldwide. Reported incidents likely represent a small percentage of pharmaceutical counterfeiting activities in a particular country. Conversely, the fact that a jurisdiction has a relatively large number of reported seizures may speak more to its enforcement efforts than to the prevalence of counterfeiting.

Table 12.2 reveals that in 2005, the jurisdictions with the most reported incidents[188] were: 1st China, 2nd Russia and 3rd the United States. However, when measured by the number of seizures, the results were: 1st Russia, 2nd China and 3rd South Korea. In 2005, based on the European Commission's TAXUD statistics, 75% of the cases of counterfeit medicines originated from India, 7% from Egypt, and 6% from China (TAXUD, 2005). It should be noted that the incidents reported in the Table represent a small percentage of pharmaceutical counterfeiting activities in any given jurisdiction. One aspect that the Table does highlight is the dearth of data available for some jurisdictions, such as the African continent, and some other developing jurisdictions.

**Table 12.2. Top 10 jurisdictions by incidents and by seizure**

| Rank by reported incidents | Total incidents | Rank by seizures | Number of seizures |
|---|---|---|---|
| 1.China | 158 | 1. Russia | 93 |
| 2. Russia | 102 | 2. China | 87 |
| 3. United States | 100 | 3. Korea | 66 |
| 4. Colombia | 71 | 4. Peru | 54 |
| 5. Korea | 67 | 5. Colombia | 50 |
| 6. Peru | 61 | 6. United States | 42 |
| 7. Brazil | 51 | 7. United Kingdom | 39 |
| 8. India | 46 | 8. Ukraine | 28 |
| 9. United Kingdom | 46 | 9. Germany | 25 |
| 10. Ukraine | 30 | 10. Israel | 25 |

*Source*: PSI, 2006.

A worrisome trend is that counterfeits are increasingly being detected as having entered the supply chain of some of the most regulated jurisdictions. For example, in 2005, "Lipitor" tablets awaiting distribution through the UK's National Health System were determined to be counterfeit (OECD Survey, 2005). Similarly, in 2003, 18 million tablets of "Lipitor" had to be recalled in the United States due to the co-mingling of counterfeit tablets with genuine tablets by counterfeiters (OECD Survey, 2005). Counterfeit products, whether or not distributed through the legitimate supply chain, violate protected IP rights.

188. The PSI (Pharmaceutical Security Institute) defines an incident as a discrete event triggered by the discovery of counterfeit, illegally diverted or stolen pharmaceuticals. PSI considers an incident to be a unique occurrence for which it must have adequate factual information, such as a particular date, time, place and type of pharmaceutical product involved. Incidents vary by magnitude, scale and timeframe. Magnitude refers to the quantity of counterfeit medicines found. An incident may involve small quantities of a single product or conversely, hundreds of thousands of counterfeit pharmaceuticals representing multiple products. Scale refers to the size of the organisation involved. Lastly, incidents can vary by timeframe. Incidents may occur over an extended period of time. An incident may be reported by anyone -- including drug inspectors, customs officials, police officers or the general public. The discovery of illegally diverted or counterfeit pharmaceuticals may be the result of government or industry market surveillance. Pharmaceutical Security Institute (PSI) (2006), "Annual Situation Report", 2005.

An examination of the data also points to an increase in the number of incidents/activities reported and prosecuted in the last few years. For example, one source reports an increase in number of incidents of approximately 27% between 2004 and 2005 (PSI, 2006). Another illustration is the recent occurrences in the UK of three types of counterfeits reaching patients through the legitimate supply chain: counterfeit "Viagra", "Cialis" and "Reductil", in 2003 and 2004. According to MHRA, these were the first cases of counterfeit drugs to penetrate the regulated UK supply chain since 1994 (MHRA, 2005). However, such increases cannot be attributed solely to an increase in counterfeiting activities, but are also a result of better surveillance, improved detection and increased prosecution. For example, in the US there was an increase of approximately 93% in the number of cases opened between 2003 and 2004, which was attributed in part to increased awareness and vigilance at all levels of the distribution chain, increased coordination between state and federal law-enforcement agencies and better communication with drug manufacturers (US FDA, 2005). Similarly, the US Customs and Border Protection reported a 144% increase of IPR-seized counterfeit pharmaceuticals from mid-2005 to mid-2006, as determined by value (US CBP, 2006*a*).

The cases mentioned above also highlight another trend, namely diversification of the types of products targeted. Examination of data for the European Union and North America reveals that counterfeiters have targeted a wide range of modern drugs, including in the areas of cancer (anti-tumor and anemia), erectile dysfunction, cardiology (cholesterol-lowering and hypertension), hormones and steroids. Counterfeiters are tempted by these high-value pharmaceuticals, especially since often they are the best-selling drugs in the world. In light of their high-value nature, these pharmaceuticals are protected by a plethora of intellectual property rights, which are registered and protected in these jurisdictions, and are violated by the counterfeits.

In developing countries, the most-often protected and violated intellectual property rights are trademarks, copyrights and less often design rights. In developing countries, the data reveal that the most commonly counterfeited drugs include the basic medicines against infection, *i.e.* antibiotics, anti-malarials, anti-retrovirals and anti-tuberculosis. For example, holograms applied to protect anti-malarials are being counterfeited, violating design rights (Newton, 2006). It has been reported that trademark infringement actions are amongst the most effective means to pursue legal action against counterfeiters. Thus, measures are taken to ensure that high-risk trademarks are recorded in as many jurisdictions around the world, where recordation is possible (OECD Survey, 2005). However, the challenge, in addition to registration, is enforcement of rights. For example, in some jurisdictions, private civil actions for trademark infringement can be expensive and time-consuming, while criminal and administrative enforcement of trademark laws may be weak. Another challenge arises when counterfeit pharmaceuticals are so prevalent that the limited resources are unable to control the problem, wherein many rights holders leave the jurisdiction, as occurred in Nigeria. Prior to 2001, when counterfeit pharmaceuticals were estimated to comprise as much as 80% of the Nigerian market, pharmaceutical companies abandoned rights (NAFDAC, 2006).

Regulation, investigation and enforcement activities in the pharmaceutical sector are governed by a multitude of legislation and regulations covering diverse fields, including regulatory approval and safety (*e.g.* drug administration, quality control, pharmaceutical distribution, importation, manufacturing, marketing, patient information, licensing practices), criminal and penal activities (*e.g.* contraband activities, racketeering, endangering life), intellectual property (trademark, patent, copyright, industrial design), customs and border activities, consumer protection, *etc*. Counterfeiting activities often will simultaneously violate a number of statutes in diverse areas. Whether an action is brought pursuant to a particular charge will depend on a number of factors including which charge will have the highest success rate and result in the most severe penalties. Criminal laws often not only provide the breadth of investigative powers and seizure authority necessary to penetrate and dismantle counterfeiting operations, but also ensure that more severe penalties can be imposed on counterfeiters. Thus, although many counterfeiting activities violate intellectual property legislation, often the prosecution will be brought under criminal law, due to the more severe penalties that can be imposed on the counterfeiters. For example, in a high-profile counterfeiting case involving a global best-selling pharmaceutical, the counterfeiter was sentenced to 13 and one-half years of imprisonment without parole and to the restitution of millions to the government (US DOJ, 2006*c*), because the action was brought under criminal law rather than IP law.

In trans-border counterfeiting, the initial determination with respect to intellectual property violations most often lies with the customs authorities[189]. Given the enormous quantities of products in all sectors that pass through borders on a daily basis and often the limited time periods in which customs authorities must deal with any given shipment, any assessment of potential violation of intellectual property rights must be made quickly. In light of this, the simplest determination of an intellectual property right violation will be a trademark, as this often only requires a visual inspection. Conversely, a determination that patent rights have been violated, in the case of pharmaceuticals, involves the more complex process of chemical analysis, which may take several days or longer. Arriving at an assessment of whether a product is infringing a process patent is even more complicated as this will require an investigation of the process used in the jurisdiction of origin for the manufacturing of the allegedly infringing good. Obviously, this results in patent infringement being alleged in border seizures only infrequently. In addition, there may be other complicating factors for determining possible patent infringement. For example, in some countries, such as the United States, patents cannot be recorded with the customs authorities. Rather, in the United States, the rights holder must obtain an order from the International Trade Commission requiring customs to exclude any product that purports to infringe a patent.

The use of trademark violations as the basis for retaining suspect products at borders is reflected in the data emerging from the European Community's Taxation and Custom Union ("TAXUD") statistics. These statistics reveal that the overwhelming percentage of intellectual property rights invoked in border seizures is trademarks (Table 12.3).

189. The term "custom authorities" is employed in a generic sense and may include customs, border patrols, etc., authorities. The powers granted to customs authorities vary considerably across the world, from search, seizure and destruction to simple detention for limited time periods.

**Table 12.3. Breakdown by type of intellectual property right covered under regulation (EC)3295/94, as % of cases**

| | Trademarks | Copyright and related rights | Designs and models | Patents and supplementary protection certificates | Data not communicated |
|---|---|---|---|---|---|
| **2001** | 83% | 9% | 5% | 3% | - |
| **2002** | 80% | 18% | 0.50% | 1.5% | - |
| **2003** | 83% | 13.5% | 1.50% | 2% | - |
| **2004** | 74% | 14% | 2% | 5% | 5% |
| **2005** | 79% | 5% | 7% | 1% | 8% |

*Source*: TAXUD, 2001-2005.

**Table 12.4. Extrapolation of number of registered cases by trademark and product type (pharmaceutical)**

2000-2004[1]

| | 2000 | 2001 | 2002 | 2003 | 2004 |
|---|---|---|---|---|---|
| Austria | 0 | 0 | 0 | 0 | 0 |
| Belgium[2] | 0.96 | 0 | 1 | 12.6 | 2.04 |
| Denmark | 0 | 0 | 0 | 1 | 0 |
| Finland | 0 | 0 | 0 | 0 | 0 |
| France[3] | 0 | 0 | 0 | 0 | 9.24 |
| Germany[4] | 226.24 | 0 | 50.4 | 6.08 | 35.28 |
| Greece | 0 | 0 | 0 | 0 | 0 |
| Ireland[5] | 0 | 0 | 0 | 0 | 0 |
| Italy[6] | 0 | 0 | 0 | 0 | 0 |
| Luxembourg | 0 | 0 | 0 | 0 | 0 |
| Netherlands[7] | 0 | 0 | 0 | 0 | 4.69 |
| Portugal | 0 | 0 | 0 | 0 | 0 |
| Spain[8] | 0 | 0 | 0 | 0 | 0 |
| Sweden[9] | 0 | 0 | 0 | 0 | 82.56 |
| United Kingdom | 0 | 2.16 | 2.97 | 89.7 | 69.72 |
| **Total** | **227.2** | **2.16** | **54.37** | **109.38** | **203.53** |

Notes:

1. It should be noted that the newly admitted member states of the European Union have not been included, since the comparative data from 2000 were not available. The new member states are Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia.

2. For Belgium in 2004, the unidentified percentage was 64%.

3. For France in 2004, the unidentified percentage was 41%; for 2002, it was 52%; and for 2001, 42%.

4. For Germany in 2004, the unidentified percentage was 60%; for 2003, it was 54%; for 2002, 41%; and for 2001, 46%.

5. For Ireland in 2004, the unidentified percentage was 40%.

6. For Italy in 2004, the unidentified percentage was 54%.

7. For the Netherlands in 2004, the unidentified percentage was 43%; for 2001, it was 47%; and for 2000, 52%.

8. For Spain in 2004, the unidentified percentage was 62%; for 2003, it was 42%; for 2002, 61%; and for 2001, 49%.

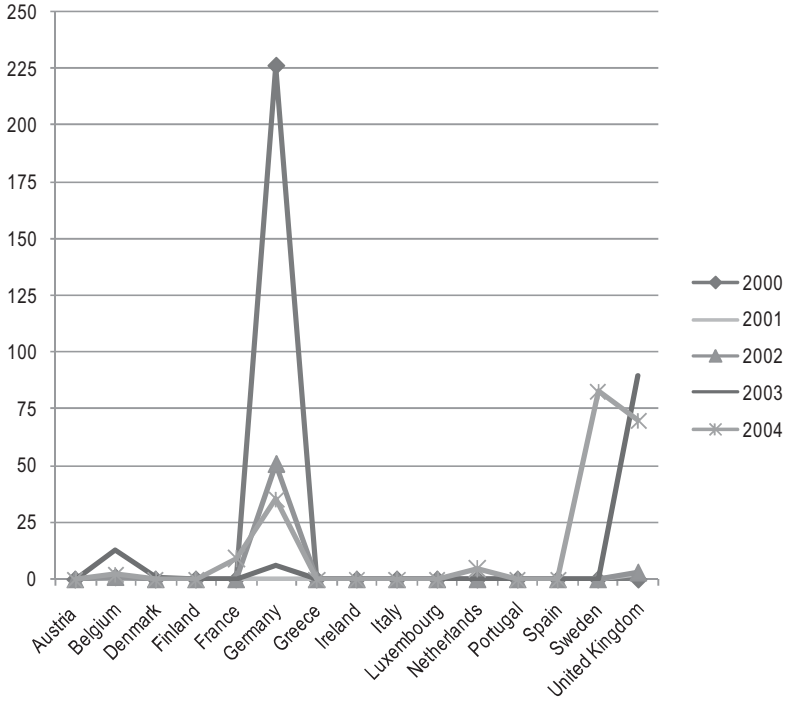
9. For Sweden in 2004, the unidentified percentage was 45%; for 2003, it was 42%.

*Source:* OECD extrapolation from TAXUD data.

This perspective of IPR violation is also borne out in the field of pharmaceuticals. The challenge to using TAXUD data is that until 2005 there was no separate category for pharmaceuticals, as there is for "clothing accessories" or "computer equipment". Rather, pharmaceuticals were part of the catch-all category "Other Goods". Table 12.4 and Figure 12.4 have been developed by extracting from the category "Other Goods" the figures that pertain to pharmaceuticals. Table 12.4 presents an approximation of the number of cases registered as trademark violations with TAXUD for the field of pharmaceuticals.[190] In 2005, TAXUD decided, for the first time, to collect statistics for seizures of pharmaceuticals as a separate category. In 2005, there were 148 cases pertaining to medicines registered with TAXUD. The breakdown of the number of medicine cases registered expressed as a percentage by origin/provenance reveals that in 2005, 75% of the cases involved provenance from India, 7% from Egypt, 6% from China, 4% from Thailand, and 1% from Argentina. The 148 cases pertaining to medicines that were registered with TAXUD constitute 1% of all the cases registered for all product types. While this data should not be interpreted as indicating that there are few counterfeit pharmaceuticals being imported into the EU, it does highlight that few cases of intellectual property rights violation are registered with the border enforcement authorities, and may highlight issues in regards to border enforcement.

**Figure 12.4. Number of registered cases by trademark, 2000-04**

Number of registered cases by trademark and product type: Other Goods - Pharmaceuticals




*Source*: OECD extrapolation from TAXUD data, (2000-04).

190. These figures are an extrapolation from the percentage of cases identified as pertaining to a particular trademark and the total number of cases per member country in the "Other Goods" category. In certain circumstances, these numbers may be skewed as the unidentified percentage of cases in the "Other Goods" category was significant (defined as over 40%).

Another reason that trademark violations are more often invoked than patent violations is that often trademarks outlast the applicable patents. An analysis of 37 counterfeit pharmaceutical incidents reported in the United States illustrates this point. The reported incidents involved 30 drugs, of which only 20 still had valid patents.[191] However, all 30 pharmaceuticals had registered trademarks that were infringed by the counterfeit products.[192]

While a global figure on the economic value of trade in counterfeit pharmaceuticals is not feasible, an examination of the potential profit from the counterfeiting of certain patented and trademark-protected pharmaceuticals provides some insight into the economic motivation underlying this activity. In the United States, some biologics have been counterfeited because they are of high value. This is the case for "Epogen Injection" and "Procrit Injection" (both epoetin alfa). Vials of "Epogen" and "Procrit" containing 2 000 U/ml of epoetin alfa were acquired by counterfeiters in the USA, re-labelled as 40 000 U/ml and re-introduced into the supply chain (Amgen, 2002; Ortho Biotech, 2002*a*, 2002*b*, 2002*c*). The theoretical profit from this crime may be calculated as follows. At the time, the cost of a vial of the 2 000 U/ml was USD 22 while the cost of a vial of the 40 000 U/ml was USD 445. The number of vials involved in this counterfeiting operation is believed to have been 110 000. Consequently, an outlay of USD 2.42 million to purchase the 2 000 U/ml vials would result in a sale price of USD 48.95 million at full price (Jaret, 2004). The actual profit obtained would have been less than USD 46.53 million since the 40 000 U/ml were sold at a discounted price in order to provide the incentive for buyers in the secondary market to purchase them and allow these buyers a mark-up leading to a profit for themselves. Even so, the potential profit is still significant as the counterfeiters simply had to remove the original labels by soaking the vials, print new labels and apply them.

## 12.5. Modes of operation

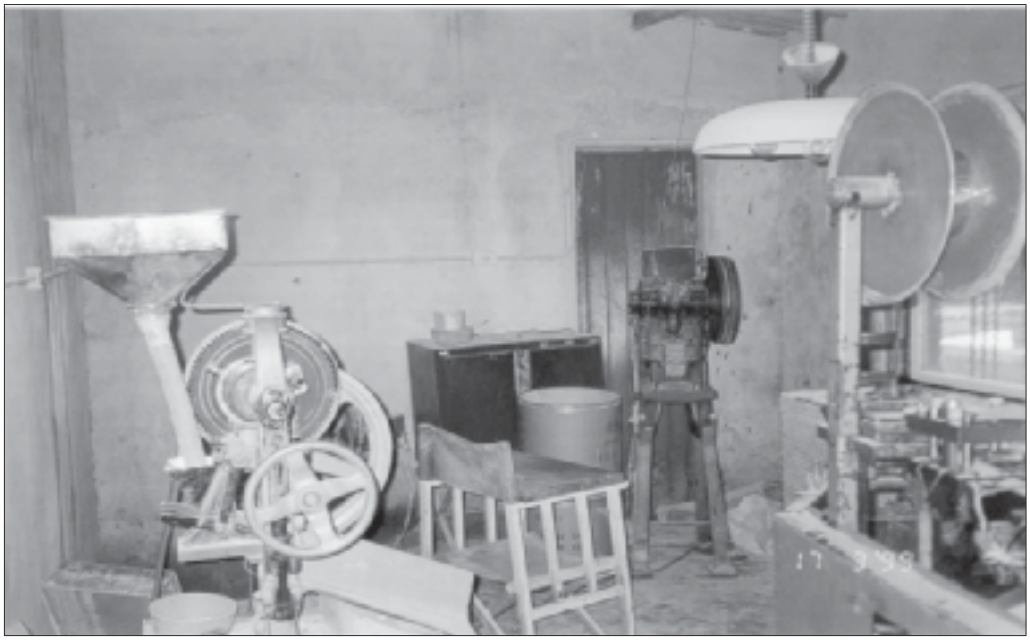
### *12.5.1. Manufacturing and production*

Within many jurisdictions, the manufacturing and production of pharmaceutical products is a heavily regulated process. Conversely, the illicit nature of counterfeit pharmaceuticals signifies that they are not subject to any regulatory process. Counterfeit pharmaceuticals, whether API or finished product, may be manufactured and produced in the most dismal and unsanitary conditions (see Figure 12.5). They are not produced according to Good Manufacturing Practices (GMP) or approved procedures and most often use unskilled workers. Counterfeit pharmaceuticals enter the legitimate supply chain through a slew of activities including grey markets, imports, "overruns" sold at a discount, diversion and theft (Beckett, 2005).

191. As indicated in the Orange Book database.

192. As indicated in the Trademark database.

**Figure 12.5. Examples of conditions of counterfeit pharmaceuticals manufacturing and production**



*Source:* Instituto Nacional de Medicamentos – ANMAT, 2006.

**Figure 12.6. Examples of equipment/technology employed**

*Source*: Name withheld.

*Source:* Instituto Nacional de Medicamentos – ANMAT 2006.

Counterfeiters are able to mass produce tablets and blister packs in significant quantities through the acquisition and use of equipment for pressing tablets, often rudimentary and not prohibitively expensive, and through the use of abundant cheap labour.

While the pictures above represent the production of counterfeit pharmaceuticals in developing countries, as the following pictures illustrate, the conditions are not greatly improved when production occurs in developed countries. Below are pictures of labs producing counterfeit pharmaceutical products in the United Kingdom that were discovered through investigation and subsequently dismantled (MHRA, 2005). Such counterfeiting activities obviously operate outside the strict regulatory framework governing pharmaceuticals (including their manufacture, labelling, safety and efficacy as well as distribution).

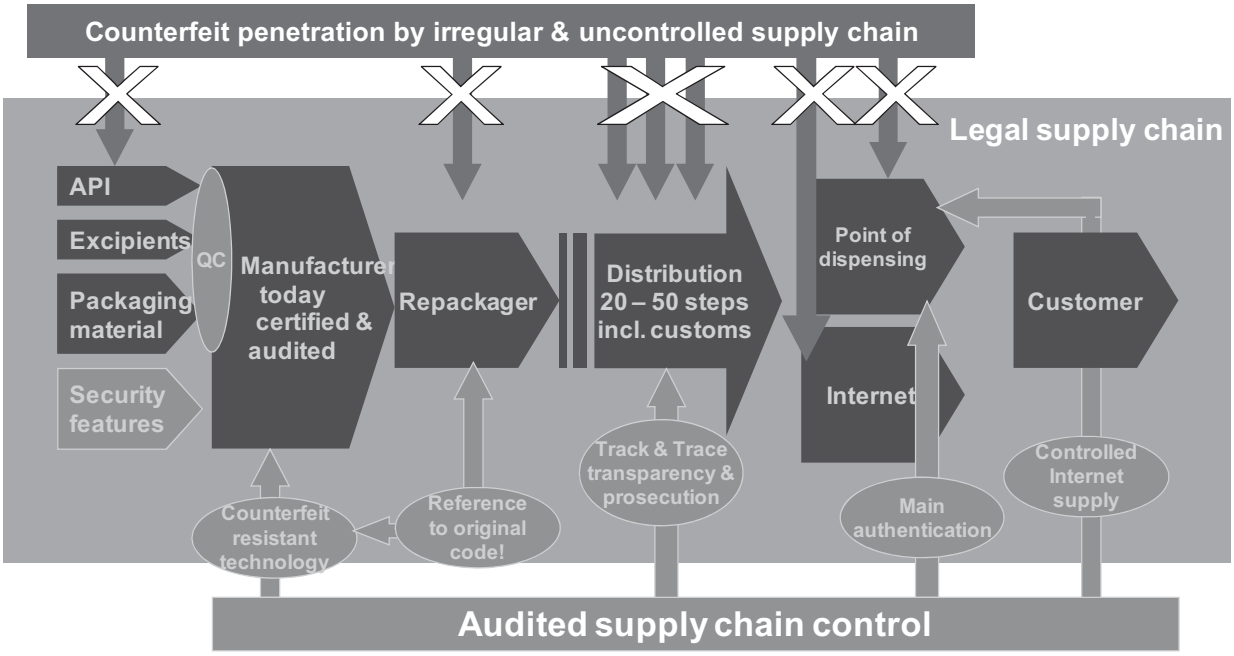
**Figure 12.7. Counterfeit operation in the UK**

*Source*: MHRA, 2005.

### *12.5.2. Distribution/supply chain*

The business of counterfeit pharmaceuticals is fluid and fast moving. While there are numerous approaches, in general, brokers or "middlemen" attempt to connect buyers and sellers through a series of "comfort transactions", in which both parties attempt to develop a level of mutual trust. A generalised view of the legitimate and illegitimate distribution channels is presented in the following graphics. The illustrations show how counterfeit products may enter the legitimate distribution channels from sources in the illegitimate channel. Note that diversion and tampering can occur at any point, but the main entry points appear to be at distribution and at retail levels.

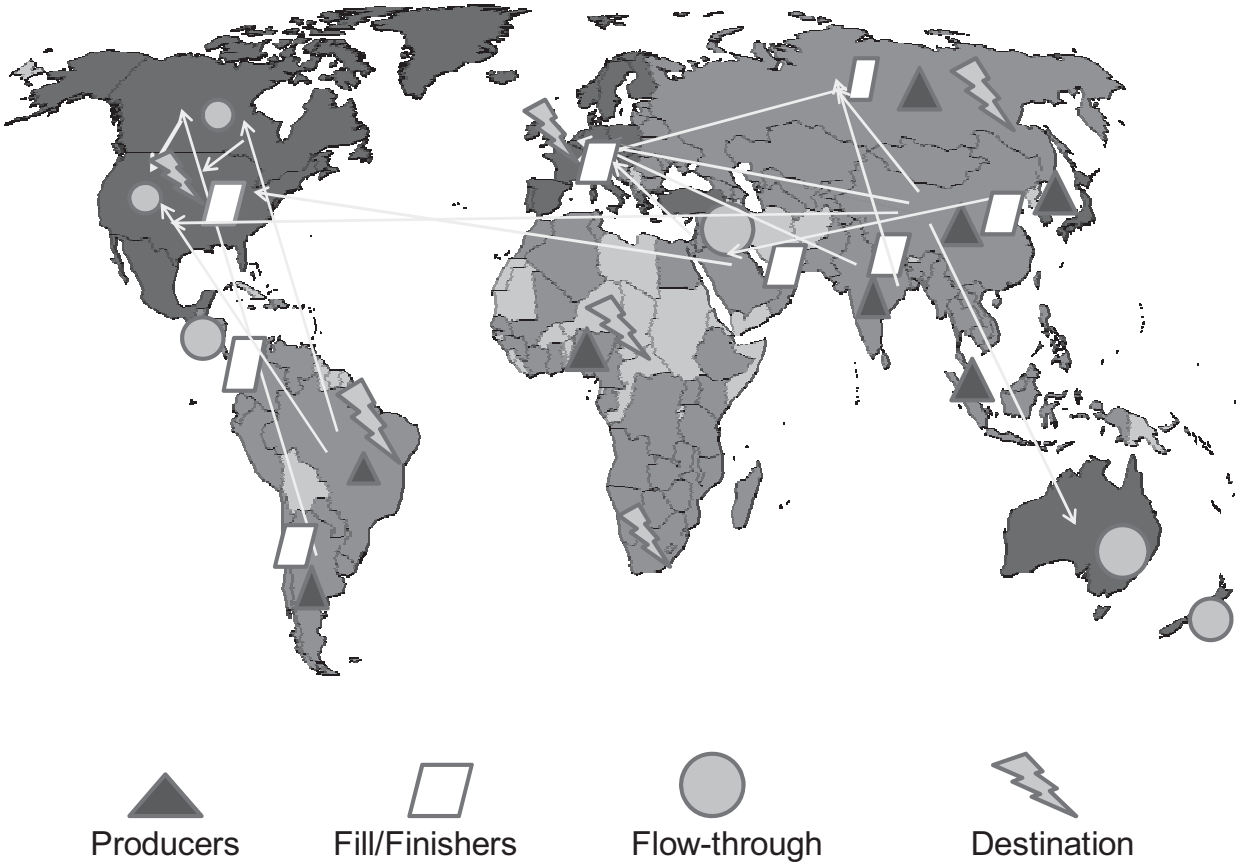
**Figure 12.8. Possible flows of counterfeits to the legitimate distribution channel**




*Source*: EFPIA 2005.

The distribution of pharmaceutical products throughout the world is complex and varies significantly from jurisdiction to jurisdiction. Many pharmaceutical counterfeiters operate on a multi-jurisdictional basis. For example, investigations have revealed that producers of active pharmaceutical ingredients in China and India distribute in Korea, Chinese Taipei, or surrounding countries for finishing and packaging (Confidential). Counterfeit products are distributed through multiple distribution channels – mainly paths of least resistance, limited law enforcement, and free trade zones. Many producers flourish in developing countries and their products are not necessarily intended for local consumption. Often the products are produced for retail pharmacies and distributors and Internet-based customers throughout the world. For example, investigations have revealed that locations in the Middle East have been identified as distribution points for counterfeit products sourced from Asia and destined for Europe (Confidential). Investigations also revealed that a free trade zone within Central America had been identified as serving as a distribution point for products destined for North America. Figure 12.9 provides examples of flows of counterfeit products. It should be noted that this provides a snapshot fixed in time, as the movement of counterfeit pharmaceuticals is constantly changing and adapts to modifications in legislation, regulation, and policies; enforcement activities; disruption; demand; new illicit gateways; etc. (Confidential).

**Figure 12.9. Example of some flows of manufacture and distribution of counterfeit products**




*Source*: Name withheld.

### *12.5.3. Internet*

The popularity of the Internet, coupled with efficient search engines, has beneficially enabled patients and consumers to seek information on health topics. Conversely, the Internet has also led to the availability of medicines from websites, and encouraged the phenomenon of consumers to self-medicate, including without the guidance of physicians or pharmacists. The willingness of patients to buy medicines through the Internet has been quickly recognised by criminals as a profitable way to supply counterfeit medicines to unsuspecting customers. Of the three types of Internet pharmacies (*i.e.* prescription, resident medical professional and non-prescription) the last category will be examined so as to highlight the concerns that arise with many Internet pharmacies. Non-prescription Internet pharmacies dispense pharmaceutical products without any prescription and without any medical professional consultation (GlobalOptions, 2003). While it would be extremely difficult to ascertain with any degree of certitude the exact number of Internet pharmacies existing, it appears that the majority of online pharmacies fall within this last category. This type of online pharmacy raises the most concern with respect to counterfeit drugs. Generally, there is no professional diagnosis, prescription or monitoring, nor is there any control of safety, efficacy or quality of the products dispensed since this type of Internet pharmacy is not subject to any legislation or regulation.

While some of these Internet pharmacies may be dispensing authentic pharmaceutical products, this type of online pharmacy may also be established by unscrupulous counterfeiters who sell counterfeit products to the unsuspecting patient. This is especially the case with websites deceptively passing off counterfeits as a 'generised' version of a pharmaceutical. As Internet websites are easily created, counterfeiters may establish an Internet pharmacy, exploit it and then dismantle it when the potential of being discovered increases. Thus, this type of Internet pharmacy presents a readily available distribution channel and may be located anywhere in the world, irrespective of its advertised location, and often without a fixed location. In April 2005, in the "Bansal" case, officials from the United States through co-ordination with numerous countries, arrested the key individuals involved in an international Internet network that illegally sold "vast quantities of controlled substance pharmaceuticals drugs and non-controlled prescription drugs" via the Internet (DOJ, 2005*c*).

### *12.5.4. Corruption, organised crime and terrorist activities*

The criminals responsible for the manufacture and distribution of counterfeit drugs range from individuals, including medical professionals such as pharmacists and physicians, to criminal groups, organised crime syndicates, rogue pharmaceutical companies, corrupt local and national officials and terrorist organisations (DEA, 2006). For example, within the Russian Federation, criminal organisations have been indentified as manufacturing and distributing counterfeit pharmaceuticals in some cases in collusion with local officials (Confidential). A survey of pharmaceutical manufacturers conducted by AIPM-CIPR in 2002, cited corruption of government authorities, political influence and lack of political will as three of the top five obstacles to anti-counterfeiting efforts. While actions have been taken, the situation has not been completely redressed (Confidential).

While the primary objective of counterfeiting activities is financial gain, in some cases, secondary objectives can include funding of political aims, such as terrorist activities. For example, the link between terrorist activities and counterfeiting was again brought to light recently in March 2006 in an indictment issued by the United States government against 19 individuals on charges of operating a global racketeering conspiracy. Profits made from illegal enterprise, including through the counterfeiting of pharmaceuticals, were reported to have been provided to an organisation listed by the US government as a foreign terrorist organisation (US Newswire, 2006).

## 12.6. Effects of counterfeiting and piracy of pharmaceuticals

### *12.6.1. Patients/consumers*

The most significant implications of counterfeit pharmaceuticals for patients are the health hazards from direct use and the loss of confidence in the health system, especially in regard to counterfeit pharmaceutical products resulting from brand theft and patent violations (OECD Survey, 2005). Pharmaceutical counterfeiting has been described as the "perfect crime" since if the patient's condition improves, there is no investigation, and if the patient's condition deteriorates, it will be attributed principally to the medical condition or disease. The loss of faith in genuine pharmaceuticals will occur in areas where drug quality is perceived as being poor and results in a loss of confidence in the health-care system and the drug regulatory authorities (Newton, 2006). This will be the case especially if drug regulatory authorities are viewed as not taking adequate action.

In developing countries, the failure of counterfeit drugs to produce the desired therapeutic effect can undermine the confidence of the public in the effectiveness of western-style medicines and can result in patients turning to traditional local herbal remedies and faith healers. Not only does the patient not get well, but in the case of the use of antibiotics, the use of sub-therapeutic doses may contribute to the development of resistant strains of bacteria (Newton, 2006). There is concern that drug-resistance may increase as a result of counterfeit pharmaceuticals. In addition, the failure of pharmaceutical products due to their counterfeit nature may result in a loss of confidence in healthcare professionals (OECD Survey, 2005). On the economic side, the purchase of counterfeit medicines not only wastes the financial resources of the patient, but when the patient does not get better, may also necessitate treatment for adverse reactions (OECD Survey, 2005).

From a clinical perspective, the negative consequences of taking counterfeit drugs are many and range from inconvenience to death. In the case of therapies for non-life-threatening conditions, the effect on health may be modest and perhaps limited to the absence of a clinical effect. Numerous cases of counterfeited "lifestyle" drugs used to treat erectile dysfunction, for example, have been reported with no API, resulting when taken, in unsatisfied customers. Unfortunately, in most cases the effect on patients is not systematically recorded. Records of the actual clinical effects of counterfeit drugs are most often kept only in cases involving successful prosecutions or multiple deaths, and thus present an incomplete picture. For example, it was reported that over 2 500 deaths occurred in Niger in the period 1995 to 1996 in a meningitis outbreak when over 50 000 people were inoculated with counterfeit meningitis vaccine that contained only water (WHO, 2006*a*). Deaths from counterfeit medicine can also occur due to the presence of toxic ingredients. There have been a number of tragic occurrences involving the ingestion of diethylene glycol, an anti-freeze agent, either as a contaminant in glycerin or as a deliberate replacement for propylene glycol. The literature points to over 350 reported deaths attributed to diethylene glycol during the 1990's in four jurisdictions (Bangladesh, Haiti, India and Nigeria). More recently, in October 2006, in Panama, at least 30 deaths were attributed to the use of four medicines contaminated with diethylene glycol (DRN, 2006).

Serious side effects can also occur when a drug has been substituted for the active ingredient stated on the label. In 2002, bottles of the antiretroviral drug "Ziagen" were relabelled as the antiretroviral drug "Combivir" in the USA (GlaxoSmithKline, 2002). While both drugs treat the same disease, approximately 5% of the patients who take "Ziagen" develop a potentially life-threatening hypersensitivity adverse reaction. If a hypersensitivity reaction occurs, patients are counselled never to take "Ziagen" again, since another dose can rapidly produce more severe symptoms that may include life-threatening hypotension and death. Since neither the prescribing physician nor the patient would know that "Ziagen" was present in the counterfeit "Combivir", the full implication of a mild hypersensitivity reaction could be missed, and the dosing could continue with severe medical consequences.

The emergence of avian influenza and the concern of its spread to humans demonstrate one of the difficulties in fighting counterfeit drugs and the possible implications for human health. There have been several cases of counterfeit "Tamiflu" in the USA, a drug which would be used in the event of a pandemic outbreak of influenza. The US Customs and Border Protection seized 51 shipments of counterfeit "Tamiflu" in south San Francisco in late 2005 and 250 parcels in New York in January 2006 (US Customs 2005, 2006). These incidents also illustrate the opportunistic nature of this criminal activity.

The acquisition of pharmaceuticals over the Internet may appear attractive to patients. From the advertisement on the website, patients may assume that they are purchasing the authentic product rather than one from an unknown jurisdiction with either no active ingredient, inappropriate levels, wrong active ingredients, toxic active ingredients, expired products with a false new expiration date, unapproved pharmaceutical products, products that have been improperly stored or transported, products that were not manufactured according to GMP, products without or with inappropriate packaging or labelling in terms of providing the patient with advice on drug usage, counter-indications, safety concerns, and potential side effects, etc. All of these factors increase the health risk for the patient. Investigations have shown that it is possible to order and receive very dangerous medicines without a prescription.[193] Studies have shown that patients purchasing pharmaceuticals over the Internet are more likely to be the subject of deceptive practices. For example, an August 2005 study showed that 85% of Internet drugs purported to come from one jurisdiction actually came from 27 other countries, including India, Costa Rica and Vanuatu (FDA, 2005).[194]

### *12.6.2. Private sector*

For the private sector, ensuring continued confidence of patients in their products, and in the healthcare system in general imposes the primary burden. For pharmaceutical manufacturers, this involves activities to secure the supply chain, investigate and detect counterfeiting activities, and prosecute counterfeiters. In many cases, the manufacturer has put in place a product security or anti-counterfeiting strategy, which involves the allocation of resources (OECD Survey, 2005). Pharmaceutical manufacturers put in place anti-counterfeiting technologies to safeguard their products, which may involve considerable investment. For example, the cost of anti-counterfeiting measures for one product in one jurisdiction has been estimated at 10%-20% of total sales per annum (OECD Survey, 2005). Moreover, pharmaceutical manufacturers must continuously update the technologies employed in order to outwit counterfeiters, who are able to copy or crack these technologies.

As reliance on technology alone is not sufficient, many large pharmaceutical manufacturers also have staff that, in collaboration with governmental authorities and police forces, carry out investigation and detection of counterfeiting activities. The operation of such investigative activities is an additional cost. While frequently the information about counterfeiting activities is shared with authorities for the prosecution of counterfeiters,

193. Schedule II and III Controlled Substances, such as the prescription painkillers "OxyContin" (oxycodone), "Percocet" (oxycodone + acetaminophen) and hydrocodone were ordered and received over the Internet without a prescription (U.S. General Accounting Office, 2004*a*, *b*).

194. See FDA News (2005), "FDA Operation Reveals Many Drugs Promoted as "Canadian" Products Really Originate from Other Countries", P05-102, 16 December 2005, www.fda.gov/bbs/topics/NEWS/2005/NEW01277.html

there are also instances in which the counterfeiter is pursued by the intellectual property rights holder. Intellectual property litigation is often a costly endeavour. Alternatively, some actions are best or only accessible to the rights holder. For example, the use of the Uniform Domain Name Dispute Resolution Policy (UDRP) is open to the rights holder against the alleged third-party registrant. A number of pharmaceutical manufacturers have employed this mechanism to close down unauthorised websites. However, where the domain name does not contain the rights holder's trademark, an UDRP action is not available.

From an intellectual property rights perspective, the potential damage to the value of the IP right, whether trademark, copyright or patent, is a direct consequence. The potential for brand dilution is especially high for famous or well known brands (Shaw, 2005). Companies are trying to ensure the protection of their valuable trademarks and IPRs around the world (OECD Survey, 2005). However, to date, there are no available statistics that counterfeiting activities are directly impacting the value of individual IPRs in the pharmaceutical sector. A corollary is the potential effect on sales of the genuine products, whether prescription or non-prescription. To some extent, sales will be impacted by the non-purchase of the genuine product as patients purchase the counterfeited product. For example, in El Salvador, the INQUIFAR (El Salvador's Association of Pharmaceutical Companies) estimates industry losses of around USD 40 million per year due to counterfeits (Encarna, 2005). Sales may also be affected by a loss of confidence if the quality, safety and efficacy of a product should it be the subject of widespread counterfeiting, and especially if it may be substituted by another product. Furthermore, sales may also be lost due to recalls of counterfeit products (Shaw, 2005).

Another corollary is the potential liability of manufacturers and others in the supply chain. The *Fagan* v. *AmerisourceBergen Corp.* case, one of the few cases brought by a victim of a counterfeit pharmaceutical product, illustrates this point (Beckett, 2005).[195] The suit was brought against the manufacturer, the wholesaler and the retailers. In a preliminary judgement, the wholesale distributor and retailer failed to have a claim against them struck out, as it was held that they were in the best position to control movement of drugs and failed to exercise the highest practicable degree of prudence and vigilance. The claim against the manufacturer failed, as it was held that the manufacturer had no duty to anticipate and prevent criminal conduct by third parties, or to design a product in such a way as to anticipate and frustrate criminal tampering. Such negligence claims against the manufacturer were reinstated on appeal, and the case was settled soon thereafter.

The counterfeiting of pharmaceuticals has spurred on the development of the anti-counterfeiting technologies industry. Previously costly technologies, such as RFID (Radio Frequency Identification Tagging), are being refined for use with pharmaceutical products. Some analysts have estimated that if RFID adoption expands to pharmaceuticals, the industry could expand considerably in the next decade (Business Insights, 2005*b*). Moreover, preventing counterfeiting activities may spur the development of new technologies.

195. *Fagan* v. *AmerisourceBergen Corp*., 356 F. Supp.2d 198, 209 (E.D.N.Y. 2004).
*Fagan* v. *AmerisourceBergen Corp. and others*, discussed in N. Beckett, "Just Say No", *Fighting IP Theft*, May 2005.

### *12.6.3. Governments*

For governments, the impact of counterfeit and pirated pharmaceutical products is an extension of the impact on patients and businesses. Where a public health authority uses government and taxpayers funds to purchase pharmaceuticals that turn out to be counterfeit, this results in a waste of financial resources, an increase in healthcare costs and the potential lack of available genuine pharmaceutical product. For example, this used to be the situation in Nigeria, where limited availability led to the purchasing of counterfeit pharmaceuticals (NAFDAC, 2006). Patients not benefiting from the therapeutic value of the genuine pharmaceutical or having adverse reactions to the counterfeit pharmaceutical may require hospitalisation, or longer hospitalisation, both resulting in increased costs for healthcare systems. In the *Fagan* case mentioned above, the patient who brought the suit required considerable additional medical attention as a result of the use of counterfeit pharmaceuticals. In addition, patients not benefiting from the therapeutic value of the genuine pharmaceutical may take longer to return to being productive members of society, which in turn has implications for themselves, their families and their employer.

Governments must also expend limited resources for law enforcement activities in order to investigate and halt counterfeiting activities. For example, the Zhejiang province, China, established a nationwide reporting and complaint hotline and a reporting centre for intellectual property violations (Li, 2006). As well, increasing reports of investigations being carried out by authorities reflect the re-orientation of resources to fight counterfeiting activities. As pharmaceuticals are more complex and sophisticated products, combating counterfeiting in this sector requires specially trained personnel, such as pharmacists, or individuals with medical/scientific training, etc. Combating counterfeiting also requires additional customs and border actions, which increase costs for the public purse. As counterfeiting activities increase, this implies even greater resources will need to be deployed. While counterfeiters take from the public purse directly when their products are purchased with public funds, they also most likely rob governments of tax receipts.

## 12.7. Measures to combat counterfeiting

Counterfeiting of pharmaceuticals is a global problem that has implications for patients and consumers, governments, companies and international organisations. In order to properly address this problem, the collaboration and involvement of all these parties is required. Moreover, it is a multi-factorial and multi-dimensional problem that requires simultaneously co-ordinated actions from all these parties. Some of the categories in which action needs to be taken in order to redress the problem of counterfeit and pirated pharmaceuticals include: the use of technology; the use of legislative and regulatory mechanisms; the strengthening of enforcement mechanisms, including through the availability of appropriate resources and international collaboration; education of, and communication with, the public; and through more stringent practices/control within the supply/distribution chain. Each of these actions may involve one or more actors working in the manufacture, distribution, sale and regulation of pharmaceutical products.

### *12.7.1. Technology*

One component for combating counterfeiting is the use of technological applications.[196] However, reliance only on technological solutions will not redress the problem of counterfeit pharmaceuticals. Moreover, the use of more than one technological solution is often required. Experience has demonstrated that even when more than one technological solution has been employed, counterfeiters are able to produce counterfeited and pirated products. The feasibility of use of a particular technology across different jurisdictions will vary in light of existing conditions and resources. Moreover, the availability of particular technological solutions will be heavily influenced by the level of economic development in a particular jurisdiction. For example, the application of RFID technologies in developing countries in Africa or Southeast Asia, where significant counterfeiting activity is occurring, may not be feasible for cost and technological reasons (Brand News, 2006). In these jurisdictions, governments, international organisations and industry are considering which type of technology would be most effective.

Currently, a multitude of technologies are applied to pharmaceutical products in order to thwart counterfeiting activities. A survey of 179 industry executives found that currently the most commonly employed security measures are, in descending order, bar codes, blister packaging and colour printing (Business Insights, 2005). While unit-of-use, such as blister packs and tamper-proof packaging, are the commonly used preventative technologies to deter counterfeiting, these are being reproduced by counterfeiters in jurisdictions where labour is abundant and inexpensive.

Overt technologies (*i.e.* visible to the eye), covert technologies (*i.e.* not visible and requiring equipment for authentication) and forensic technologies are increasingly being employed as anti-counterfeiting measures. Nevertheless, highly complex holograms have been copied by counterfeiters with such detail that it was impossible to detect the counterfeit with the naked eye (Newton, 2006). So as counterfeiters become adept at reproducing technologies, manufacturers need to continuously modify and increase investment in the technologies they employ. For example, an international pharmaceutical manufacturer is carrying out trials of employing forensic technologies (*i.e.* DNA security labels) in Latin America (Brand News, 2006). If the trials are successful, the company intends to use the item-level DNA labels to replace the currently employed holograms as its anti-counterfeiting measure. Two components, one in the label and the other in the reader, produce a colour change if a product is genuine. However, the upgrading and continuous modification of technologies also raises its own challenges, including, for example, increased costs, and ensuring that the supply/ distribution chain is aware of the nature and timing of the changes.

Many consider track-and-trace technologies as forming an important component for combating counterfeiting. While there are a number of track-and-trace technologies, each with different characteristics and advantages, only two examples are discussed herein: 2-D Bar Codes and Radio Frequency Identification tagging (RFID). The adoption of any given technology is a complex question involving issues, amongst others, of cost, compatibility, feasibility and reliability, and there are divergent views on which technologies should be adopted and the timing for their adoption.[197]

196. The in-depth technical examination of each of the technologies referenced is beyond the scope of this chapter.

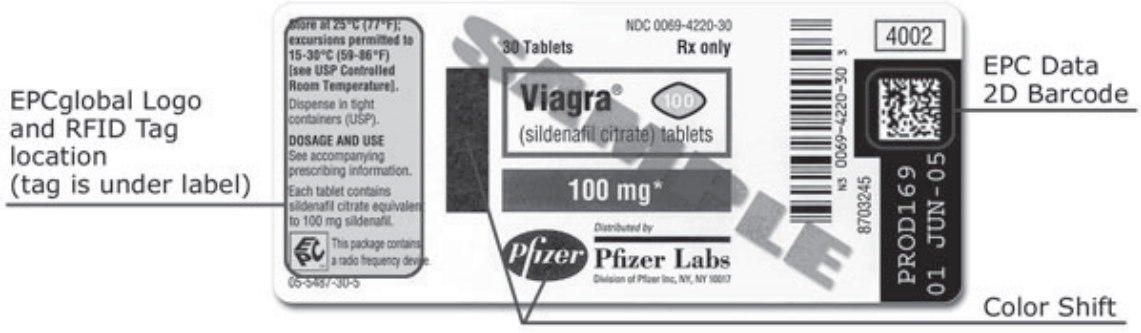
197. It is beyond the scope of this report to recommend the use or adoption of any given technology.

2-D (*i.e.* data-matrix) barcodes are a more sophisticated version of the black-and-white barcode, in that they may permit storage of increased information along the height and length of the symbol and can be used in very small applications. Employed in the distribution of pharmaceuticals, the use of 2-D barcodes would permit the storage of significantly more information, such as lot number, expiration date, reimbursement information and other data. It is being advocated as an anti-counterfeiting measure for use within the European Union, in light of the complex supply chain (EFPIA, 2006). It is advocated that the use of a unique, randomised (*i.e.* not sequential) serialised number for each secondary packaging unit distributed and sold across Europe will enable identification and verification across the entire supply chain, thereby improving transparency, patient safety and combating counterfeiting (EFPIA, 2006). In a repackaging scenario where the product and barcode would be separated, the 2-D barcode would no longer fulfil its purpose. The use of 2-D barcodes is viewed as complementing the eventual use of RFID tags (EFPIA, 2006).

Although the use of RFID (Radio Frequency Identification Tagging) technology continues to be viewed as expensive, it is beginning to be explored within the pharmaceutical sector (Brand News, 2006). Given the relative newness of using RFID technology for pharmaceuticals, in 2004, a pilot programme called the "Jump-Start Initiative" was carried out in the United States by a network of 14 companies – pharmaceutical manufacturers, wholesalers and retailers in collaboration with the US FDA; bottles and cases of selected drugs were tagged and then traced throughout their supply chain journey. The trials permitted product pedigree information to be accessed in real-time via a web portal. Through recall or diversion simulations, unknown or missing products (as well as those whose expiration date was soon to be reached) were singled out and dealt with, and recalls were facilitated, as the location of the product was known. The pilot project was deemed a success. The US FDA continues to advocate a phased-in approach to the adoption of RFID technology by the pharmaceutical sector starting with products most vulnerable to counterfeiting and diversion. The US FDA also recognises that there remain numerous outstanding issues with RFID which will need to be addressed (US FDA, 2006*c*).

Some pharmaceutical manufacturers are considering, or have begun to incorporate, the use of RFID into the packaging of their products (Business Insights). For example, by December 2005, Pfizer ensured that every package, case and pallet of "Viagra" (sildenafil citrate) shipped in the United States contained RFID tags (Pfizer, 2006). To date, Pfizer's application is not yet capable of "tracking and tracing" pharmaceutical products through the entire distribution system, because complete track-and-trace requires that all actors within the supply chain invest in the compatible technology and agree to capture and share information about product movement (Pfizer, 2006).

**Figure 12.10. Sample of the Viagra label highlighting the security features**




*Source:* Pfizer, 2006.

RFID technology for use on pharmaceuticals is still under development as there remain a number of outstanding issues (Confidential). There are issues pertaining to costs as the unit price for a RFID tag is considered still relatively high, and tracing equipment for downstream segments is also capital intensive. The cost issue continues to be a barrier for complete rollout for all pharmaceutical products, even within developed countries. This is an even greater concern for pharmaceutical products supplied to developing countries, where marginal differences in prices are significant. Concerns pertaining to equipment persist. For example, tags and readers continue to fail. Concerns also pertain to data standards. The establishment of standards could also play an important role in lowering costs. However, depending on the nature of the standard, it could also increase costs and complexity. Concerns also exist about the effect of RFID on the product quality/integrity. While these concerns may not arise for most products, they centre on the interaction between the RFID tag and different types of pharmaceutical products or their packaging, such as biologics, liquids and foils. Issues pertaining to the maturity of the technology in terms of its readability and reliability persist. Challenges pertaining to the access, ownership and sharing of information throughout the supply chain continue. The rate and speed of adoption of a RFID system across the supply chain is another issue. Privacy concerns have been expressed as certain versions of the tags have the ability to collect patient information, and it is unclear where and how such data would be captured and maintained. Finally, as noted above for the 2-D barcodes, in a repackaging scenario where the product and tag would be separated, the tag would no longer fulfil its purpose.

### *12.7.2. Legislative and regulatory mechanisms*

The combating of counterfeiting relies on a combination of a multitude of legislation and regulations covering a broad spectrum of areas, including: intellectual property (trademark, patent, copyright, industrial design rights); regulatory approval (*e.g.* drug administration, quality control, pharmaceutical distribution, importation, manufacturing, marketing, patient information, licensing practices); enforcement; custom and borders; consumer protection; and criminal and penal activities (*e.g.* contraband activities, racketeering, endangering life). While pharmaceutical counterfeiting is first and foremost a public safety concern that involves countries' health and safety legislation, intellectual property and criminal law are also important.

The lack of adequate legislation, regulation and especially enforcement and penalties, are often invoked as weaknesses that counterfeiters exploit. This is especially noted for the legal systems of many economies in transition or developing economies. For example, Nigeria is working to remedy the inadequacy of its legislation for combating counterfeit pharmaceuticals by developing guidelines. Moreover, the myriad of applicable legislation and regulations produce another obstacle to effective and efficient prosecution. The challenges also often lie in the application of the legislation and regulations. This brief overview will highlight the challenges from an intellectual property perspective. It is a difficult and complex determination, and beyond the scope of this report, to assess legislation and regulation.

A survey covering the legislation and regulations of a number of countries reveals that many jurisdictions, including ones often viewed as major sources of counterfeit pharmaceuticals, have in place a system of legislation and regulation that provides recourse against counterfeiting activities (PhRMA, 2006). For example, Brazil, China, India and Russia, all have enacted trademark laws that provide for both civil and criminal remedies. In these cases, both fines and terms of imprisonment are options available to the deciding authorities. Often, there are even graduated levels of fines and terms of imprisonment. Similarly, legislation covering the active pharmaceutical ingredient, the finished product and the packaging are in place. However, very few jurisdictions have enacted laws that specifically address pharmaceutical counterfeiting, *per se*, or the full range of upstream and downstream activities that contribute to the manufacture and supply of counterfeit medicines.

While the remedies may be available, one challenge is the non-application or the inefficiency of these remedies and measures (PhRMA, 2006). For example, in China there is a reluctance to invoke criminal remedies against trademark counterfeiters, which is exacerbated by high quantitative and monetary thresholds that in many cases preclude criminal enforcement against commercial counterfeiters (PhRMA, 2006). While provisional measures are available on an *ex-parte* basis pursuant to the PRC trademark law, and while courts are required to decide an application within a 48-hour period, often the timeframe varies between two weeks and one month before a decision is rendered. In Russia, civil actions are virtually not employed due to the difficulty of obtaining provisional measures, which courts are reluctant to grant. Parties must rely on the use of the criminal or administrative actions available for trademark infringement. In Brazil, law enforcement authorities lack *ex officio* powers to investigate trademark counterfeiting offences (PhRMA, 2006).

Another problem is judicial and administrative systems and their agents that are overwhelmed (PhRMA, 2006). In India, for example, due to the sheer volume of litigation, judicial delays are common. In India, as a result of the complex structure of the local police and metropolitan magistrates, inadequacy of police resources and inexperience of prosecutors, particularly in the specialised field of pharmaceuticals, there is a low conviction rate (*i.e.* about 2%). However, in some metropolitan cities, IPR Cells that have jurisdiction to investigate and prosecute trademark counterfeiters across the entire city are being established.

There are numerous legislative and regulatory lacunae. For example, the Russian trademark law does not expressly provide for injunctive relief or provisional measures. While these are available pursuant to the Russian Civil Code, they are practised in a limited manner. Similarly, in India and in Brazil, administrative remedies are not available for trademark infringements, except with respect to border enforcement. In Brazil, civil actions are more favoured against trademark counterfeiters, given that rights holders must bear the significant burden of prosecuting criminal actions. Good manufacturing practices (GMP) and good distribution practices (GDP), for example, are not in place in many jurisdictions. Legislation regulating Internet pharmacies is lacking in most jurisdictions. For example, Brazil, India, Russia and many OECD countries do not have legislation or regulation targeting the sale and distribution of pharmaceuticals through the Internet.

However, within some jurisdictions, measures specific to counterfeiting of pharmaceuticals are being undertaken. For example, the European Commission has developed a draft Directive that would provide for criminal measures for the violation of IPRs. The International Pharmaceutical Federation has developed Good Pharmacy Practice (GPP) guidelines with a view to providing assistance to pharmacists and others in developing countries (FIP, 1998).

### *12.7.3. Education and communication with the public/patients*

Education and communication with patients and the public with respect to counterfeit pharmaceuticals raise a number of challenges. Public education and communication about counterfeit and pirated drugs must involve all stakeholders. The information must be accurate, delivered in a manner that is accessible to the average non-expert individual and provided by a trusted entity. In case of an incident, the information must be timely, but neither cause fear nor prompt patients to discontinue using their prescription pharmaceuticals. In terms of general education of the public about the dangers of purchasing and using unapproved pharmaceuticals or obtained from unapproved sources, the information must be communicated in a balanced manner, by trusted professionals, so as to not cause alarm and distrust in the health system. In order to be the most effective, this type of communication will also need to take into account cultural differences.

At the international level, the International Council of Nurses has published information and an action toolkit entitled "Counterfeits Kill" (ICN). This publication has the dual purpose of educating nurses and national associations of nurses, as well as the general public, about the nature of counterfeit pharmaceuticals, and providing them with the tools required for better detection of counterfeits. For example, it contains a "Tool for the Visual Inspection of Medicines". This document has been used by nurses to carry out education campaigns, in collaboration with industry and public health authorities.

At the government level, numerous public education and information campaigns have been undertaken both in developing and developed jurisdictions. In order to be most effective, such initiatives need to be tailored to the circumstances existing within a given jurisdiction, to the needs of the population and to the culture of that jurisdiction. For example, Nigeria's national medicines regulatory agency has undertaken a "Public Enlightenment Campaign" that involves dialogue, education and persuasion of the public in order to achieve behavioural change, so that the use of counterfeit pharmaceuticals from open-air markets is halted (NAFDAC, 2006).[198] Many pharmaceutical regulatory

198. Discussions with authorities.

agencies provide information for both patients/the public and for pharmacists. A number of governments, including the German Ministry of Health, the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and the US Food and Drug Administration, provide information on their respective websites for the public about counterfeit pharmaceuticals, as well as information about the purchase of pharmaceuticals over the Internet. Recently, MHRA and the Royal Pharmaceutical Society of Great Britain issued "Guidance for Pharmacists" and a "Guidance for Patients", in order to assist both of these groups in detecting and reporting incidents of counterfeit and pirated pharmaceuticals (MHRA, 2006*a*, *b*).

### *12.7.4. Enforcement*

There are a number of challenges faced by authorities in enforcement activities against counterfeit pharmaceuticals. As examined above, the multitude of complex legislation that is applicable and administered by different entities within any government is an enormous challenge when aiming to combat counterfeiting activities. Thus, the first challenge for most governments, whether developed or developing, is to ensure proper co-ordination and communication between the various entities involved in enforcement activities. Another significant challenge is that not all jurisdictions have put in place agencies for monitoring, tracking and combating counterfeiting activities in a co-ordinated manner, both nationally and internationally. For example, the Argentinean "Division Fraude Marcario" (*i.e.* Fraudulent Marks Division) was created at the beginning of 2006. The Italian government is intending to establish a Task Force in order to monitor and evaluate the phenomenon of counterfeited pharmaceuticals, to co-ordinate activities of diverse entities and to establish countermeasures.[199]

International efforts at co-ordination include work by the World Custom Organization, Interpol, the establishment of the Pharmaceutical Security Institute and the World Health Organization's IMPACT. The limited or lack of resources, whether human or financial, for enforcement activities is another key obstacle to redressing the problem. Of 841 arrests reported in 2005, 230 were made at points of distribution[200] and 214 at the point of sale (PSI, 2006). Such data provide some guidance to enforcement authorities for allocating their limited resources in the most effective manner. Enforcement also involves the collaboration between private sector investigations and law enforcement authorities.

Policing of Internet pharmacies is a complicated activity, and generally involves co-operation of national and international law enforcement agencies and the private sector. For example, the US FDA has undertaken measures to identify and shut down fraudulent and illegal Internet pharmacies. Its approach is to carry out criminal investigations, that can involve arrests, and to issue warning letters to both domestic and foreign pharmacies. In 2005, the US Drug Enforcement Agency concluded an investigation that dismantled a large online counterfeit prescription drug ring. This operation shut down 200 illegal Internet pharmacies. Similarly, states and state medical boards are also aiming to shut down illicit Internet pharmacies. For example, in 2002, New York prosecutors charged individuals and companies for making and selling counterfeit "Viagra". The investigation uncovered a distribution ring that stretched from fake pill mills in China and India to Internet sellers in Nevada and Colorado (GlobalOptions, 2003). Pharmacy boards as well

199. Discussions with authorities.

200. Distributors report that wholesalers and individuals were arrested at warehouses where counterfeit goods were being stored.

as medical professional associations have also begun to take disciplinary actions against Internet pharmacies. In Canada, where the dispensing of pharmaceutical products is regulated by provincial Colleges of Pharmacists, the policy of the Ontario College prohibits Canadian Internet pharmacists from entering into agreements for the purpose of co-signing or re-writing prescriptions for out-of-country residents. In 2002, the Ontario College of Pharmacists filed charges against an Internet pharmacy for unlawfully operating an unlicensed pharmacy (GlobalOptions, 2003).

In order to address the issue of counterfeit sales of medicines over the Internet, some countries have established, or are considering establishing, mechanisms for ensuring safe and efficacious Internet pharmacies. The National Association of Boards of Pharmacy (NABP), which represents the state boards of pharmacy within the USA, eight Canadian Provinces, two Australian States, New Zealand and South Africa, developed the Verified Internet Pharmacy Practice Sites (VIPPS) programme in 1999. This voluntary programme certifies pharmacies that comply with the licensing and inspection criteria of their state and each state to which they dispense drugs, according to the NABP criteria. The VIPPS programme provides a way for patients to verify the authenticity of Internet sites selling drugs but has a limited number of registered sites (12 sites in May 2006), which may not be known to the public. In 2006, the Royal Pharmaceutical Society of Great Britain prepared a Guideline that gave comprehensive advice to pharmacists who provide Internet pharmacy services.

The private sector also carries out investigations and undertakes legal actions against fraudulent and illicit Internet websites. Often an entity will register numerous domain names bearing similar or misleading information to attract patients. Companies use the Uniform Domain-Name[201] Dispute Resolution Policy (UDRP) process of the ICANN [202] in order to deal with unauthorised websites that use trademark protected terms, such as "Viagra" (OECD Survey, 2005). This administrative process provides efficient, relatively inexpensive, as compared to litigation costs, and fast resolution to the abusive use of a domain name. Nevertheless, its effectiveness is limited since it applies only to top-level domain names incorporating trademarks and does not prevent the registration of additional domain names. e-Bay, the Internet trader, has in place a programme called VeRO ("Verified Rights Owner"), through which it implements its "notice and take down" policy (e-Bay, 2006). In addition, e-Bay permits pharmaceutical sales by e-pharmacies only if these are licensed.

201. The Domain Name System (DNS) helps users find their way around the Internet. Every computer on the Internet has a unique address called its "IP address" (Internet Protocol address). Because IP addresses (which are strings of numbers) are hard to remember, the DNS allows a familiar string of letters (the "domain name") to be used instead. Rather than typing "192.0.34.163," one types "www.icann.org".

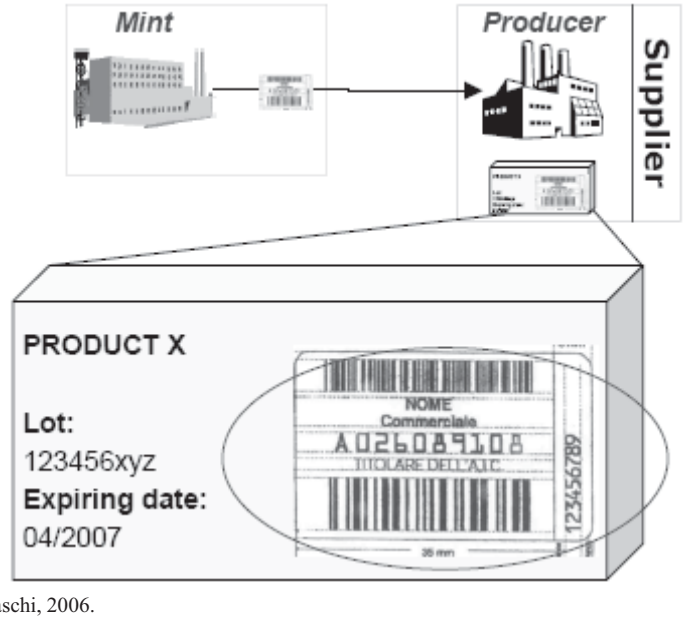
202. www.icann.org/new.html. WIPO Arbitration and Mediation Centre – Domain names Disputes: http://arbiter.wipo.int/domains/guide/index.html.

### *12.7.5. Securing the distribution/supply chain*

#### *12.7.5.1. Government action*

Certain governments are undertaking a number of proactive measures to better secure the distribution/supply chain for pharmaceuticals. Each government is employing a combination of legislative, regulatory and technological approaches. For example, in Europe there are the *Guidelines on Good Distribution Practice Medicinal Products for Human Use* and in the United States, both at the national and at the state level, there is legislation pertaining to the supply chain (*i.e.* the pedigree requirements). In Europe, a number of countries, such as Italy, Belgium and Spain, have put in place, or are putting in place, systems for better tracking products with the objective of securing the supply chain. Although each system is different, the idea is that pharmaceuticals may be tracked from manufacturing through distribution to dispensing. A positive aspect of these systems is that they permit comprehensive tracking of pharmaceuticals throughout the supply chain in the given jurisdiction. However, some have expressed concerns that if each jurisdiction within Europe were to adopt a unique system, this could result in a fragmented market and could involve increased costs for manufacturers (EFPIA, 2006). Concern has been expressed that some of these systems may affect patient privacy.

**Figure 12.11. Bollino System**




*Source*: Bergamaschi, 2006.

To illustrate the functioning of these types of systems, the Italian approach will be briefly outlined. In order to combat fraud and counterfeiting, Italy will implement tracking, through the "bollino" ID system, which will collect and store information in a central database. This approach is possible since within Italy, pharmaceuticals are almost all pre-packaged. The national mint (INZP) produces the unique "bollino" labels that are sent to the pharmaceutical producer/supplier. Each pharmaceutical will be affixed a "bollino" displaying: *a)* the AIC code of the drug; *b)* the product's denomination; *c)* the AIC owner; and *d)* the progressive identification of the single package – unique identifier. The "bollino" will enable the tracking of each package from the manufacturer down to the point of dispensing.

#### *12.7.5.2. Private sector action*

In light of the complexity of the distribution and supply chain in many jurisdictions and the potential this has for the entry of counterfeit pharmaceuticals, some manufacturers have adopted new approaches to the distribution of their products. For example, in the UK, Pfizer announced that it will no longer distribute through its major wholesalers (Hawkes, 2006). Instead, it decided that it will distribute its products to pharmacies and dispensing doctors with the aid of a single delivery company, UniChem. This will guarantee at least one source of authenticate products to pharmacies and hospitals. It has been indicated that this measure will have no effect on prices (Hawkes, 2006). Similarly, Johnson & Johnson decided that it will sell only to distributors who agree to its contractual terms, which stipulate that they cannot purchase from other distributors and re-distributors. Eli Lilly and Company is taking similar actions to enhance its supply chain through wholesale contracts, monitoring and auditing of the supply chain (Shaw, 2005).

## 12.8. Conclusion

The counterfeiting of pharmaceuticals is a global concern that has serious implications for patients and consumers, governments, companies and international organisations. Although the establishment of precise figures is extremely difficult, this activity appears to be on the rise. While it is first and foremost a global public health problem, counterfeiting of pharmaceuticals also has significant implications for intellectual property rights. As a global concern, it needs to be addressed on a global scale. Properly addressing this problem requires the collaboration and involvement of all parties. Moreover, it is a multi-factorial and multi-dimensional problem that requires simultaneous and co-ordinated actions from all parties.

Some of the categories in which action needs to be taken in order to redress the problem of counterfeit and pirated pharmaceuticals include: the use of legislative and regulatory mechanisms; the use of technology; the strengthening of enforcement mechanisms, including through the availability of appropriate resources and international collaboration; education of, and communication with, the public; and through more stringent practices/control of the supply/distribution chain. Each of these actions may involve one or more actors working in the manufacture, distribution, sale and regulation of pharmaceutical products.

**Table 12.5. Propensity drivers to production and consumption of counterfeit pharmaceuticals**

| PRODUCTION | CHARACTERISTICS |
|---|---|
| ***Market characteristics*** | |
| Unit profitability | **Profit margins can be very large**<br>While the unit cost, and therefore profitability, varies depending on the amount of genuine active ingredient used, on the sophistication of the packaging and labelling, and on the number of products sold, there is still a significant profit margin to incite counterfeiters, even in developing countries where the price of pharmaceuticals is much lower. |
| Market size | **Larger market in jurisdictions with weak regulations and enforcement**<br>There is a much larger market for counterfeits in jurisdictions where regulation and enforcement is weakest, such as many developing countries. There is a much smaller market for counterfeits in jurisdictions with strong regulation, which make penetration more difficult, as is the case for most developed countries. However, no country is immune to counterfeit pharmaceuticals, irrespective of its level of development. |
| Genuine brand power | **Strong in developed countries; less strong in developing ones**<br>In developed countries, the brand of the pharmaceutical will be very strong, especially for blockbuster and prescription "lifestyle" drugs. However, in developing countries, since the most commonly used pharmaceuticals are essential medicines, the brand tends to be less important. |
| ***Production, distribution and technology*** | |
| Production investments | **Investment required varies with sophistication**<br>The level of investment will vary according to how sophisticated the counterfeit is. Investments are required for numerous elements including for purchasing bulk ingredients, to produce the counterfeit, the packaging, the labelling and for access to the distribution system. This is even more significant if there is a trans-border element. However, the investment required to produce a crude counterfeit and distribute it locally can be quite modest. |
| Technology | **Technology not excessive barrier**<br>Technology required to produce counterfeit products, packaging and labels is for the most part rather easily accessible. Copying more advanced technologies is a challenge/obstacle, but for a relatively short period of time. |
| Logistics | **Logistics are a complicating factor, especially in heavily regulated jurisdictions; Internet facilitates the penetration of counterfeits even in heavily regulated jurisdictions.**<br>It is much more difficult to bring a product to a physical market that is heavily regulated, as is the case with developed countries. The penetration of counterfeits in jurisdictions with weak regulation and enforcement is much easier. The Internet facilitates the penetration of counterfeits into markets, whether developed or developing. |

| | |
|---|---|
| Marketing and sales of products | **Quite difficult to penetrate the supply chain in developed jurisdiction; easier to penetrate supply chain in developing countries. Internet provides parallel supply chain, greatly facilitating penetration.**<br><br>It is quite difficult to penetrate the legitimate distribution channels in heavily regulated jurisdictions, such as those of developed countries. Easier to penetrate distribution channels in jurisdictions with weak regulations, such as in developing countries. The Internet creates the opportunity for separate distribution channels not requiring the penetration of a regulated supply chain. |
| Ability to conceal operation | **Moderately more difficult in developed jurisdiction, easier in developing jurisdictions.**<br><br>The ability to conceal a counterfeit pharmaceutical operation is easier in jurisdictions with weaker regulatory systems, where resources and monitoring activities are lowest. The ability to conceal is more difficult within jurisdictions with strong regulatory frameworks and the resources to investigate. |
| Ability to deceive | **Deception very necessary**<br><br>The key element for a successful counterfeit pharmaceutical is that it is accepted by the consumer as genuine. Thus, the counterfeit must be sophisticated enough to pass off for the genuine product, packaging and label. The more sophisticated the genuine product, its packaging and labelling, the more costly it may be for the counterfeiter to reproduce. |
| ***Institutional characteristics*** | |
| Risk of discovery | **Higher risk of discovery in heavily regulated jurisdictions; moderate rate of detection in jurisdictions with weak regulation.**<br><br>In heavily regulated jurisdictions, the risk of detection is higher, especially when there are important resources allocated to the detection of counterfeiting activities. However, in many jurisdictions where the regulatory framework is weaker, and where there are no, or limited, resources for investigating counterfeiting activities, the risks are much lower. The risks are also lower for activities carried out over the Internet. |
| Legal and regulatory framework | **Extremely complicated framework**<br><br>The legal and regulatory framework for pharmaceuticals is extremely complicated, involving a multitude of diverse fields, including: regulatory approval (*e.g.* drug administration, quality control, pharmaceutical distribution, importation, manufacturing, marketing, patient information, licensing practices); criminal and penal activities (*e.g.* contraband activities, racketeering, endangering life); intellectual property (trademark, patent, copyright, industrial design); customs and border activities; consumer protection, etc. Some jurisdictions have a weak legal and regulatory framework. Often, even when legislation exists, prosecution is difficult for a multitude of reasons. |
| Enforcement | **High if detected in developed jurisdictions; weaker in developing jurisdictions.**<br><br>Enforcement action will be taken against detected counterfeit activities in developed jurisdictions. Enforcement has been considered to be much weaker in developing jurisdictions. |
| Penalties | **Penalties deter where imposed**<br><br>The application of penalties to detected counterfeiting acts as a deterrent. However, the challenge is to ensure that appropriate penalties are provided for in the legal and regulatory framework, and that they are applied to the counterfeiters. |

| CONSUMPTION | CHARACTERISTICS |
|---|---|
| ***Product*** | |
| Price | **Developed jurisdiction, no price difference; developing jurisdictions and Internet, significantly lower price.**<br>*Physical distribution network:*<br>In developed countries, the objective is that the counterfeit pharmaceutical enters the legitimate supply chain, so the end price to the consumer at the pharmacy will be the same. However, the counterfeiter profits by having cheap production costs, and so the profits realised are significant. In developing countries, the lower price of counterfeits, coupled with the lack of knowledge of the difference between the counterfeited and genuine products, increases the propensity to purchase.<br>*Internet:*<br>The lower prices advertised on Internet sites increases the propensity to purchase, especially since these products are seen as genuine. |
| Quality and nature of product | **Critical element – expectation of same therapeutic effect**<br>Whether in developed or developing jurisdictions or purchased over the Internet, the expectation is that the medicine will have the therapeutic effects that it is intended to have. |
| Ability to conceal status | **Not an issue for physical distribution; easy to conceal for Internet purchases.**<br>For the physical distribution, there is no issue. For Internet purchases, once products are in hand, the ability to conceal is relatively easy, especially since the product is consumed. |
| **CONSUMER** | |
| Health & safety concerns | **Extremely high**<br>The health and safety concerns of consumers in regard to the consumption of counterfeit pharmaceuticals are extremely high. The challenge is that many consumers are not informed of what constitutes a counterfeit and the associated health hazards and are thus unable to detect counterfeits. |
| Personal income | **Higher prices and/or lower incomes create higher incentives for consumers to seek counterfeits**<br>In jurisdictions where medicines are available at accessible prices to the population, there is less incentive for consumers to seek alternative sources of medicines and therefore expose themselves to counterfeit medicines. In jurisdictions where incomes are low and/or the price of medicines is high, there is higher incentive for consumers to seek alternative supplies of pharmaceuticals, thereby increasing their risk of purchasing counterfeit medicines. |
| Personal values | |
| ***Institutional*** | |
| Risk of discovery | **Very moderate for Internet purchases**<br>A consumer seeks to know of counterfeits in the legitimate supply chain so as to avoid them. The likelihood of detection for the consumer who purchases over the Internet is very small. If the Internet purchase crosses borders, the risk of detection is somewhat higher. |
| Risk of prosecution | **Very low**<br>Low risk of prosecution of consumers. |
| Penalties | **Varies, but low risk**<br>Depending on the legislation, the applicable penalties may be the same as for the counterfeiter. However, there is low risk of prosecution. |

| | |
|---|---|
| Availability and ease of acquisition | **In developed jurisdictions, physical acquisition is quite difficult; physical acquisition in a developing jurisdiction and on the Internet is much easier.**<br>Acquisition of counterfeits is quite difficult in heavily regulated jurisdictions. In jurisdictions with weak regulatory frameworks and over the Internet, acquisition is easier. |
| Socio-economic factors | **Education and awareness play an important role**<br>The less educated and the less informed are at greater risk of purchasing and using counterfeits. Irrespective of the level of development, education and awareness play an important role in deterring the purchase and use of counterfeits. |

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