# 6 The push factors behind counterfeit pharmaceuticals

Why is the pharmaceutical market so attractive for counterfeiters? This chapter explores this question, analysing how the profitability of this criminal venture – combined with low risk of detection, low risk of prosecution and weak penalties – have contributed to its steady growth.

The decision of what counterfeit product to produce and which markets to target is driven by factors related to: 1) the characteristics of the market, which determine market potential; 2) technological and logistical considerations, which determine the feasibility of counterfeiting; and 3) the institutional environment, which determines the risks of being caught.

Table 6.1 assesses the situation for pharmaceuticals, based on a general framework and analysis presented in OECD (2008). As shown, the pharmaceutical market can be highly attractive for counterfeiters.

### Table 6.1. Framework for assessing the attractiveness of counterfeiting pharmaceuticals

| Driving factor | Conditions favouring counterfeiting pharmaceuticals | Situation for pharmaceuticals |
|---|---|---|
| **Market characteristics** | | |
| Profitability | High unit profitability and/or large volume | Can be very large, especially if cheap ingredients are used |
| Market size | Large potential market | Pharma market is large (more than USD 1 trillion) and growing |
| Brand power | High level of brand recognition | Strong brand power |
| **Production, technology and distribution** | | |
| Investment required | Simple, low cost equipment | Cost of making crude fakes can be modest; a pill press may suffice |

| | | |
|---|---|---|
| Technology required | Not sophisticated; easy to acquire | Production technology, packaging and labeling challenges vary; can be easy, or a significant challenge |
| Logistics | Simple and cheap | Shipping costs are low; free trade zones have facilitated trade in fakes |
| Marketing and sale of products | Easy to establish/infiltrate distribution channels | Difficult to infiltrate principal supply chains; easier if second tier wholesalers targeted; Internet has facilitated trade in fakes |
| Ability to conceal operations | Easy to hide illicit operations | Can be easy if operations are on a small scale |
| Ability to deceive consumers | Easy to deceive consumers | Easy to deceive visually; anti-counterfeiting technology can complicate significantly |
| **Institutional characteristics** | | |
| Legal and regulatory framework | Weak laws | Complicated situation in many countries makes it difficult to prosecute |
| Enforcement | Weak enforcement | Enforcement levels vary across countries; clever counterfeiters often succeed in avoiding enforcement efforts |
| Penalties | Weak sanctions | Criminal sanctions provided for in many countries; fines are generally a manageable cost of business in many countries |

*Source*: Based on OECD (2008), *The Economic Impact of Counterfeiting and Piracy*, https://doi.org/10.1787/9789264045521-en.

## Profitability

The sale of counterfeit medicines can be highly profitable and highly attractive to organised crime groups, especially when the amount of expensive active ingredients used in the counterfeits are reduced. For some products the active ingredients can account for 80% of the cost of a generic medicine (WHO, 2017b). According to the pharmaceutical company Pfizer, who produced the innovative medicine, Viagra (one of the most counterfeited medicines worldwide), the production of 1 kilogramme of heroin has higher costs and lower street value than the respective costs and profit entailed by the production and distribution of 1 kilogramme of Viagra, meaning that the profit margins for Viagra are much higher (UNICRI, 2012). In one case investigated by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom, 100 000 counterfeit pills imported at the price of about GBP 0.25 each were being sold for up to GBP 20 each, which translates into a profit margin of 7,900%.

## Low risk of detection

In international trade, customs officials are most likely to encounter potentially low-quality medicines before they enter a country, and health care workers are most likely to spot them once they do (WHO, 2017b). It is rare, however, for either of these groups to have access to simple field tests that would help them to triage suspect products. Moreover, where field testing equipment is available, staff do not always have the training or the time to use it correctly.

In an assessment of the regulatory capacity of 26 countries in Africa published in 2010, the WHO concluded that these countries did not generally have the capacity to control the quality, safety or efficacy of the medicines circulating on their markets or passing through their territories. Detection of counterfeit medicine by custom officers is difficult due to the limited time for analysis of the shipments. Additionally, many criminals engaged in pharmaceutical counterfeits use original packaging but manipulate the pharmaceuticals. Of 20 samples of seized suspected counterfeit pharmaceuticals analysed by Dégardin and Roggo (2016), all packaging was found to be authentic with the exception of one vial, which was a different shape and size. In three samples, pharmaceuticals have been found to be genuine and in 17, they have been confirmed to be counterfeits. Five samples consisted of genuine chemical composition but manipulated packaging. In one case chemical content was totally counterfeited. In case of 11 counterfeits, the samples were of genuine origin but the medicines had been diluted with water, with the dilution factors ranging from 1.5 to 200. Half of the samples had a different batch number on the vial than on the box. While the counterfeit was confirmed within one to two days of detection of suspected shipments, one week was needed for the full forensic analysis of the composition (Dégardin & Roggo 2016).

## Low risk of prosecution

The risk of prosecution for counterfeiting pharmaceuticals is low (WHO, 2017b). Most counterfeits are only detected when they reach retailers or patients and it is frequently difficult to trace them back through complex supply chains, or to prove where criminal activity occurred. Moreover, in most countries, investigation of criminal activity is the work of the police, who may not have extensive expertise in the specialised techniques sometimes needed to investigate pharmaceutical crime. The situation is further complicated because the international nature of trade in counterfeits often requires cross-border investigation, which can be difficult, especially if the criminal parties involved have complex ownership structures and use foreign bank accounts. Difficulties in following paper trails of investigated products to trace their point of origin can be significant as the location of evidence necessitates forensic examination of computers and smartphones, some of which may be in foreign jurisdictions. Language barriers can also affect cross-border co-operation.

## Weak penalties

In most countries, sentences for falsification of medical products are far less than those applicable to, for example, drug smugglers, who can be imprisoned for lengthy terms and can have the proceeds of their crimes confiscated (WHO, 2017b).

Table 6.2 compares information on maximum prison terms in selected countries for trademark infringement and narcotics trafficking (OECD, 2018c).

### Table 6.2. Maximum incarceration for trademark infringement and narcotics trafficking

In years

| | Brazil | Canada | France | United Kingdom | United States | Average |
|---|---|---|---|---|---|---|
| Trademark infringement | 1 | 5 | 4 | 10 | 10 | 6 |
| Narcotics trafficking | 15 | 10 | 10 (or life sentence in certain cases) | Up to life sentence | Up to life sentence | 25[1] |

*Note*: [1]Life sentence is approximated at 50 years.
*Sources*: OECD, 2018c and www.inhouselawyer.co.uk/wgd_question/are-there-criminal-sanctions-for-infringement-of-any-intellectual-property-rights-and-if-so-what-are-they-and-how-are-they-invoked/#France.

Table 6.3 shows the sanctions and maximum incarceration periods for trademark infringement in the BRICS countries.

In addition to criminal sanctions, rights holders can sue for damages. Alternatively, as shown in Table 6.3, they can seek compensation through statutory penalties; such penalties are not available in all countries. Other fines can also be applied. In the case of statutory damages, the amounts that can be recovered, when provided for, vary significantly among countries. In the case of the United States, they can reach up to USD 2 million (OECD, 2018).

### Table 6.3. Selected features of trademark regimes in Brazil, China, India, Russian Federation and South Africa, 2016

| Item | Brazil | China | India | Russian Federation | South Africa |
|---|---|---|---|---|---|
| Statutory damage | x | ≤ USD 430,000 | x | ≤ USD 72,000 | x |
| Administrative civil fines | x | ≤ 5x illicit gain (1) | x | ≤ USD 2,900(2) | x |
| Criminal sanctions: imprisonment up to … | 1 year | 7 years (3) | 3 years | 6 years (4) | 5 years (5) |
| Other fines | ✓ | x | ≤ USD 2,900 | ≤ USD 14,000((6) | ≤ USD 650 (7) |

*Notes*: National currency amounts have been translated into USD, based on average exchange rates in 2016 (see, www.irs.gov/individuals/international-taxpayers/yearly-average-currency-exchange-rates). (1) If the illicit revenue is less than USD 7 200, or is not known, a fine ≤ USD 36 000 can be imposed. (2) Applicable to legal entities. (3) Applicable to cases which are deemed to be serious in nature. (4) Applicable when a group of persons or organised group of infringers is involved. (5) For repeat offenders; first offence is for up to 3 years. (6) Applicable to groups; fine can also be calculated on the basis of an amount equal to up to 5 years wage or salary, or other income, of a convicted person. (7) For repeat offenders; first offence is up to USD 376.
*Source*: OECD, 2018c.

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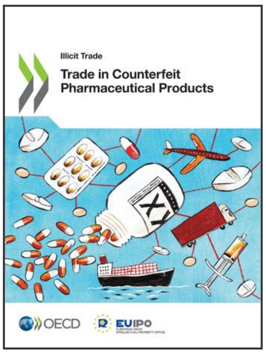


**From:**

# Trade in Counterfeit Pharmaceutical Products

**Access the complete publication at:**

https://doi.org/10.1787/a7c7e054-en

**Please cite this chapter as:**

OECD/European Union Intellectual Property Office (2020), “The push factors behind counterfeit pharmaceuticals”, in *Trade in Counterfeit Pharmaceutical Products*, OECD Publishing, Paris.

DOI: https://doi.org/10.1787/88de56c2-en