

7 Impact of counterfeit medicines

Why are counterfeit medicines such a problem and who is affected? This chapter explores in depth the multiple ways in which fake pharmaceuticals cause damage – to individuals' health, to the bottom line and reputation of producers, to government budgets and to the environment.

Counterfeit medicines affect economies in a number of areas:

- Individuals who fall victim to low quality counterfeit products that may not adequately treat their medical needs.
- Legitimate producers, who can lose sales to counterfeiters, and need to take steps to ensure that counterfeiters do not infiltrate their supply chains, and to mount efforts to combat counterfeiters.
- Governments, which are actively involved in managing health care in countries.
- Entire economies, in the form of the impact on crime levels, the environment and the possible effects on jobs and foreign investment.

It is often assumed that high-income countries with strong regulatory systems can effectively exclude substandard and falsified medical products from their markets, but WHO analysis shows that this is not necessarily the case, as reports on these products have been submitted by countries in Western Europe and North America as well as other high-income settings (WHO, 2017b). In an analysis of cases of counterfeit incidents involving penetration of legitimate supply chains and reported to PSI CIS database between 2009 and 2011, Mackey et al. (2015) revealed that upper and lower-middle income countries comprised 93% of all the cases. Analysis of the health consequences of falsified medicines performed by Rahman et al. (2018) showed that the 48 reported incidents involving health damage due to falsified medicines were almost equally distributed among developing (27 cases, 56.3%) and developed countries (21 cases, 43.7%).

Impact on individuals

Bad quality counterfeit medicines can affect individuals in a variety of ways (WHO, 2017c):

- Adverse effects (for example toxicity) from incorrect active ingredients.
- Failure to cure or prevent future disease, thereby increasing mortality, morbidity and the prevalence of disease.
- Contributing to the progression of antimicrobial resistance and drug-resistant infections.
- A loss of confidence in health care professionals, health programmes and health systems.
- Increasing out-of-pocket and health system spending on health care.
- Lost income due to prolonged illness or death.
- Lost productivity costs to patients and households when seeking additional medical care, the effects of which are felt by businesses and the wider economy.

As indicated above, people taking counterfeit medicine may be putting their lives at risk. Estimates show that between 72 000 and 169 000 children may die from pneumonia every year after receiving counterfeit drugs, and that fake anti-malarial medication might be responsible for an additional 116 000 deaths (WHO, 2017c). Renschler et al. (2015) estimate that each year over 120 000 under-five malaria-positive children may die across 39 sub-Saharan countries due to taking poor-quality anti-malarials, including counterfeit and substandard pharmaceuticals. In their rather conservative review of the published literature on the health consequences of falsified medicines, Rahman et al. (2018) analysed 48 reported incidents in which falsified medicines caused serious adverse effects to patients. These incidents involved approximately 7 200 casualties, including 3 604 deaths. The results of the study indicate that a similar number of incidents affect developing and developed countries alike, and the counterfeiters target all types of medications (Rahman et al. 2018).

Forensic tests of suspect samples performed by the pharmaceutical industry also demonstrate that counterfeit medicines, in 90% of those cases tested, could cause harm to the patient (Novartis in Society Report, 2019).

While many incidences of patient harm will likely go undetected, numerous examples have nevertheless been recorded.¹ For example, a recent UK survey carried out by Sapio research and commissioned by a private company INCOPRO, concludes that almost one-third (32%) of those who have bought one or more counterfeit medicines have suffered a health issue as a result (INCOPRO, 2020). There are numerous other documented cases in which patients have died or suffered harm due to an online purchase. As just one example, in 2013 people died after taking a counterfeit diet pill bought through an online drug seller. The pill, sold as a weight loss aid through many illicit online pharmacies, is actually a pesticide with lethal consequences for humans.²

Impact on producers

The impact of counterfeits on legitimate producers are multiple, including lost sales, costs of protecting brands, loss of reputation, the potential cost of managing the disposal of counterfeits and litigation costs involving counterfeiters and possibly people who were unknowingly victimised by counterfeits. The challenges are alluded to in corporate reports, albeit in a general manner. For example, one of the five largest pharmaceutical companies – Pfizer – mentioned counterfeiting in its 2019 annual financial report, although not in its general annual report.

In the financial report, the company includes a section on counterfeit products, containing general information on the challenges it faces, and noting the efforts it has taken to address the situation (Pfizer Inc., 2019a; 2019b):

“We undertake significant efforts to counteract the threats associated with counterfeit medicines, including, among other things, working with the FDA and other regulatory authorities and multinational coalitions to combat the counterfeiting of medicines and supporting efforts by law enforcement authorities to prosecute counterfeiters; assessing new and existing technologies to seek to make it more difficult for counterfeiters to copy our products and easier for patients and healthcare providers to distinguish authentic from counterfeit medicines; implementing business practices designed to protect patient health; promoting public policies intended to hinder counterfeiting; working diligently to raise public awareness about the dangers of counterfeit medicines; working collaboratively with wholesalers, pharmacies, customs offices, and law enforcement agencies to increase inspection coverage, monitor distribution channels, and improve surveillance of distributors and repackagers, and using data analytics and risk assessment tools to better target the factors that give rise to the counterfeiting problem in the first place. However, our efforts and the efforts of others may not be entirely successful, and the presence of counterfeit medicines may continue to increase.”

Novartis includes an identical paragraph on counterfeits in both its annual report and its annual financial report, describing the dangers that the practice could have on patients and the firm’s reputation (Novartis AG, 2019a; Novartis AG, 2019b). It notes that the industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. It indicates that counterfeiting of their products could result in substantial reputational and financial harm.

In its most recent annual report, Roche Group includes a section on counterfeiting that details the effects that fakes can have on patient health (Roche Group, 2019). It indicates that the global trading system opens up possibilities for introducing counterfeit products into the regular supply chain, and that it collaborates on international criminal investigations to address problems. The firm uses its internal analytical skills to examine samples of counterfeiting. Besides identifying the composition of counterfeits, analyses comprise also the ink on packaging and leaflets, blisters and paper. Counterfeits from different parts of the world are examined to determine whether they originated from the same source. In 2018, the company closed 377 suspected cases of counterfeiting, of which 142 were confirmed.

Merck addresses the challenges associated with counterfeiting in its annual report (Merck KGaA, 2019):

“To combat product-related crime, an internal coordination network covering all functions and businesses (the Merck Anti-Counterfeiting Operational Network) was set up several years ago. In addition, security measures are in use to protect products against counterfeiting. Innovative technical security solutions and defined preventive approaches are used to ward off dangers relating to cybercrime and espionage. Measures to prevent risks and to prosecute identified offenses are conducted in all the relevant crime areas in close and trustworthy cooperation with the responsible authorities. The impact of these risks on business operations depends on the respective individual case, product-specific factors, the value chain and regional aspects in particular. Our Corporate Security department is responsible for the overall coordination of all measures in this area. Overall, the threat resulting from crime in general is seen as being possible and is classified as a medium risk.”

Although counterfeiting is not mentioned in the MSD annual financial report it does however document certain trademark infringement litigation (Merck & Co., Inc, 2019). The term counterfeit does not appear as such in either the annual report or the annual financial report of Johnson & Johnson (Johnson & Johnson, 2019a; Johnson & Johnson 2019b).

Loss of revenue

The sale of counterfeit products in many instances displaces sales from legitimate pharmaceutical companies. The most recent EU Status Report on Infringement (EUIPO, 2019) estimates that the European pharmaceutical industry³ was losing EUR 9.6 billion in sales due to counterfeits during the period 2012-2016, which represent 3.9% of total sales. In China, unauthorised production of a drug produced by an international pharmaceutical company resulted in a drop in sales to about USD 242 000 (OECD, 2016). When the counterfeiting ceased in 2003, sales grew to USD 1.2 million. In 2003, the turnover from India's pharmaceutical industry was estimated at USD 4.2 billion; of this, counterfeiters produced an estimated USD 1 billion (OECD, 2016).

Increased costs of security measures

Incorporating anti-counterfeiting technologies into their products and packages raises the costs for legitimate pharmaceutical manufacturers (OECD, 2016). The costs of introducing a unique identifier for manufacturers and parallel importers have been estimated by European Commission at EUR 50 to 320 million annually. These costs relate to adapting production and packaging lines and investing in software systems to upload the unique identifier information onto the repository system. The estimation of costs for the entire sector (including manufacturers, wholesalers, retailers and repositories systems) ranges between EUR 200 and 800 million.⁴ Firms incorporate overt, covert and forensic technologies depending on the risk and sophistication of counterfeiters; many also monitor their products in the markets of counterfeit-prone countries and conduct their own investigations into reported counterfeiting incidents. As noted in a recent report by the Institute of Medicines of the National Academies, multinational pharmaceutical companies have invested in security departments that work globally with regulators and law enforcement agencies. These departments collect 80% of the evidence used in criminal prosecution (IOM, 2013).

Damage to brands

As with other forms of counterfeiting, fake medicines risk damaging a firm's brand and the products involved when those products do not meet expectations. Moreover, the firm's reputation for safety and quality are put at risk, and the firm may be subject to liability if consumers are harmed by counterfeit versions of their drugs (OECD, 2016).

Undermining innovation

Innovation is key to the success of pharmaceutical companies and to improving health outcomes. In recent decades, new medicines have improved survival rates and the quality of life for many patients around the world, while improving treatment of diseases such as HIV and certain cancers (OECD, 2018b). R&D is central to innovation; however, it is risk-prone, costly and, as indicated earlier, time consuming, with much of the risk and costs borne by private enterprises and investors. R&D is promoted in large measure by the protection of intellectual property rights, without which innovators would be hard pressed to profit from the sizeable investments required to develop new products. Infringement of IP through counterfeiting undermines innovation by reducing incentives to invest and innovate, and by depriving pharmaceutical companies of revenues, thereby lowering the amount of money available for further R&D (Tracit, 2019).

The impact of counterfeiting on pharmaceutical innovation can be particularly significant for developing countries (OECD, 2016). Less than 10% of global health research expenditures are directed to conditions that account for more than 90% of preventable mortality – conditions that are prevalent in developing economies.

Impact on governments

Counterfeit pharmaceuticals can result in squandered health resources, not only for individual patients, but also for international humanitarian organisations, NGOs and national government programmes (OECD, 2016). Counterfeiters divert resources away from genuine treatment, robbing limited health budgets of already scarce resources. At the same time, counterfeits can mean losses in corporate taxes and VAT, increased regulatory and enforcement costs for securing the supply chain, and higher health care costs to treat the adverse effects of fake drugs. With respect to taxes, EUIPO (2016) estimates that the cost to EU governments of revenues foregone from counterfeit medicines was in the order of EUR 1.7 billion.

Greater regulatory and enforcement costs

The total costs of regulatory and enforcement measures in the pharmaceutical area are not generally available as they are combined in overarching budgets of the agencies involved (OECD, 2016). While there are tools available to detect counterfeits, they can be costly. Much depends on the nature of the counterfeit products, which can be classified as follows (IOM, 2013):

- Category 1: Completely fraudulent products with unknown content and therapeutic effects significantly different from the genuine drug.
- Category 2: Look somewhat similar to the drug being imitated, but the drug composition is not known.
- Category 3: Look very similar or identical to the genuine product but contain an entirely different drug, if any.
- Category 4: Look very similar or identical to the actual product but contain an alternative drug or synthetic analogue providing similar therapeutic value to that of the authentic product, and intended to create repeat business.
- Category 5: Visually identical, highly sophisticated copies or synthetic analogues with some therapeutic value that cannot be detected using most field and laboratory methods.

In some instances, visual inspection will suffice; in others tests may be needed for physical properties such as disintegration, using reflectance spectroscopy, and refractive index; and chemical tests including colorimetry and dissolution, chromatography, spectroscopic techniques and mass spectrometry (IOM, 2013). Modern science has opened up immensely powerful and expensive forensic chemistry techniques that can give investigators information on the unique fingerprints that manufacturers leave on their products. This analysis can give prosecutors the evidence necessary to link falsified drugs to particular sources. Such analysis, however, can be too costly to apply in a general manner. Forensic chemistry assays cost between USD 5 000 and USD 15 000 per test on average. While extremely accurate, they are therefore not practical for routine product quality market surveillance in any country and may be out of reach entirely in many of the low- and middle-income countries most affected by counterfeiting problems.

Loss of confidence/trust in governments and public health programmes

Genuine harm, even among a small number of patients, can lead to a loss of confidence in government programmes and health care systems (OECD, 2016). Incidents of therapeutic failure and drug resistance can destroy the credibility and success of health programmes; counterfeit and substandard medicines will only undermine consumers' trust further and can have future knock-on effects, such as the decrease in the quality of contraceptive pills in Brazil in the late 1990s. IOM (2013) reports that rumours about contraceptive quality linger, showing the type of long-term damage that can occur.

Increased health care costs

Counterfeit medicines may also result in higher health care costs, as patients may require additional treatment to deal with potential adverse effects of ineffective or damaging drugs. Physicians and health care providers rarely suspect counterfeit or substandard drugs as the reason for a patient's poor therapeutic response. Accordingly, they most frequently respond by ordering more tests or repeating the course of treatment (OECD, 2016).

Economy-wide effects

In addition to the direct effects on consumers, producers and governments, counterfeits can have broader, economy-wide effects in a number of areas, including on the environment, foreign investment and crime. There may also be impacts on economic performance; EUIPO (2019) reports that counterfeits result in an estimated EUR 16.5 billion of lost sales and affect more than 80 000 jobs in the pharmaceuticals sector and other sectors that sell goods and services to it.

Environmental pollution

While the pharmaceutical industry is required to meet environmental protection standards and reduce chemical waste and other hazardous materials in their production processes, the same does not hold true for manufacturers of counterfeit drugs, who can reap the financial benefits of dirty production by taking environmental shortcuts (Tracit, 2019; OECD, 2016). Producers of illicit pharmaceuticals disregard the impact that chemical compounds may have on the environment, disposing of toxic dyes and chemicals without regulatory oversight, while ignoring the treatment of wastewater streams (OECD, 2016). Authorities note that seized counterfeit electronic goods and counterfeit chemicals and pharmaceuticals are particularly difficult to dispose of in an environmentally friendly manner, as the core ingredients of fake drugs are in most cases unknown, hence the environmental damage they can pose is also difficult to assess *ex ante*.

Lost foreign investment

The prevalence of counterfeit medicines on a national market may reduce or discourage foreign investment, as potential investors judge that their interests will not be protected (OECD, 2016). The consequences may constitute significant lost opportunities for economic growth and development as well as for improvements in the national health care system.

Costs of tackling complex criminal networks

Criminal involvement in the manufacture and distribution of counterfeit pharmaceutical products is of concern as it provides those involved with a source of revenue to support a wider range of illicit activities and can undermine confidence in public institutions, such as law enforcement. Investigations have uncovered significant evidence that organised criminal groups (OCGs) have expanded their illicit activities into the field of counterfeit medicines (UNICRI, 2012). A 2014 INTERPOL report examines the role of OCGs in pharmaceutical crime, finding involvement ranging from small clusters of 3 to 10 members, to larger well-established hierarchical groups and sophisticated international networks with elusive structures (Table 7.1) (INTERPOL, 2014). Analysis by Hall et al. (2017) showed that actors involved in the illicit supply of medicines “often belong to loosely structured networks. These networks straddle what are often presented as the dichotomies of licit/illicit, online-offline and global/local.” Often legitimate companies serve as a shield for trade in counterfeit pharmaceuticals. “Suppliers on all levels can operate under the guise of a legitimate company and sell illicit medicines for extra income, while using it to expand their network and launder profits” (Hall et al., 2017). The increasing use of the Internet to sell counterfeit and illicit medicines has resulted in growth in the latter form of criminal enterprises. The networks are difficult to target due to the ease with which they can move and establish new websites, the high level of anonymity offered in the virtual world, and the difficulty in piecing together the different criminals involved in wide-ranging affiliate networks.

Table 7.1. Pharmaceutical cases possibly involving organised crime groups, 2013

Region	Case
Africa	Nigeria. One person was arrested for smuggling counterfeit medicines from China to Lagos, Nigeria. The illicit medicines included Coartem, Ibuprofen and Maloxine. The scale of the smuggling operation indicates that there was involvement of an OCG.
Asia	Philippines. Philippine authorities arrested traffickers attempting to ship slimming pills, pain relief medication and antibiotics which had been shipped from Singapore. Customs authorities confiscated a 40-foot container loaded with 20 pallets of fake medicines. Connections to a trading company indicates that the case is tied to an OCG. Japan. Between 2011 and 2013, an OCG called Azuma-Gumi was running a counterfeit medicine operation selling Viagra, Cialis and Levitra in Japan. Six people were arrested.
Europe	Russian Federation. Russian authorities reported that they had dismantled a counterfeiting operation which had been ongoing for several years in Russia. Fake medicines such as Herceptin, Meronem, Cefobit, Mantera and Sulperason were manufactured and distributed by an OCG. Seven suspects were arrested.
Oceania	New Zealand. Three suspected counterfeiters were arrested with doping substances and Tadalafil in New Zealand. The three suspects were part of an OCG which distributed fake medicines in the country. The investigation revealed that the group's leader was operating a sophisticated ring of distributors and using a pill press to make tablets, as well as an improvised lab in a garage.
South America	Colombia. Police arrested 21 suspects in an operation in which a total of 89 754 units of fake medicines were confiscated. The OCG involved falsified expiration dates and batch numbers of medicines. Guatemala. Ten people were arrested as part of an operation to take down an OCG. The group had a leader and operated from a legitimate pharmaceutical company, which was licensed to produce medicines. The OCG used the company to cover production of illegal medication in order to increase the company's revenues.

Source: INTERPOL (2014), *Pharmaceutical Crime and Organized Criminal Groups: An analysis of the involvement of organized criminal groups in pharmaceutical crime since 2008*, www.reajetus.com/wp-content/uploads/2016/04/Pharma-Crime-Sub-Directorate.pdf

Authorities are also addressing related issues, including corruption within the legitimate pharmaceutical community and a lack of dedicated national enforcement units to tackle the issue (INTERPOL 2014). The challenge is heightened by the fact that criminals are increasingly using the Internet to carry out their activities and are, in turn, developing sophisticated techniques to avoid detection. Some INTERPOL member countries face legislative challenges in thwarting those responsible for pharmaceutical crime, as few countries appear to possess specific legislation to target this type of crime. Furthermore, many countries cited weak penalties as a contributing factor to the proliferation of criminal networks, who are willing to continue to take risks as the rewards outweigh the potential penalties.

Key findings from the INTERPOL report are:

- Criminals involved in pharmaceutical crime are operating through informal networks, but traditional organised crime groups across the globe are also involved throughout the supply chain.
- An increase in pharmaceutical crime occurred in some countries during 2008-13, especially in South and Central America.
- Both informal networks and organised crime groups seem to be trafficking in the same types of illicit medicines: erectile dysfunction medication; slimming pills; as well as pain and anxiety relief medication.
- An important trend in many countries is the increased use of illicit online pharmacies, operated by both informal networks and organised criminal groups.
- Large amounts of money are involved in the transnational criminal enterprises: one illicit online pharmacy network earned USD 55 million during two years of operations.
- Other crimes, such as money laundering, human trafficking for sexual exploitation and weapons smuggling, can be tied to criminals involved in pharmaceutical crime.

Cases pursued in the United States provide further insights into the role of criminal organisations in marketing counterfeit medicines:

- In April 2019, six people were charged in the US Federal Court with operating a wide-ranging drug conspiracy that included importation of large amounts of drugs which were then used to produce counterfeit Xanax pills, using Alprazolam as the main ingredient and binding agents. The illicit ingredients were purchased on the Dark Web using cryptocurrency, with the counterfeit Xanax likewise sold on the Dark Web or through conventional illegal drug distribution channels.⁵ If convicted on multiple charges (conspiracy to possess with intent to distribute controlled substances, using or maintaining a drug premises, possession with intent to distribute controlled substances, possession of a firearm in furtherance of a drug trafficking crime, possession of an unregistered firearm and conspiracy to commit money laundering) two of the defendants could face life imprisonment.
- In January 2019, the president of a medical company was sentenced to 26 months in prison for conspiring to smuggle misbranded pharmaceuticals into the United States and for the unlicensed wholesale distribution of prescription drugs.⁶ The individual concerned instructed subordinates to smuggle misbranded prescription drugs and devices into the United States, including oncology drugs, orthopedic injections, and cosmetic devices. These products were not approved by the Federal Drug Administration (FDA) and did not contain the labels, warnings, and instructions required by the FDA. In order to smuggle these products into the United States, the company used false names and false customs forms, and broke large shipments into multiple smaller shipments. The products were stored in private residences, often in violation of safety regulations requiring the pharmaceuticals to be stored at cool temperatures.
- In March 2018, a US federal grand jury returned a 28-count indictment charging four individuals with mail and wire fraud conspiracy, mail fraud, trafficking in counterfeit goods, introducing misbranded articles into interstate commerce, distribution of a controlled substance, international money laundering, and smuggling.⁷ The individuals sought to enrich themselves by purchasing from overseas suppliers FDA-regulated products that were counterfeit and/or misbranded, illegally importing them into the United States from the People's Republic of China and subsequently selling them to US consumers. In an effort to evade detection by law enforcement, the defendants had the packages shipped to a trans-shipper located in Miami, Florida, who would then re-package and/or re-label the parcels and send them to defendants in Puerto Rico, where they were warehoused. The products were then marketed through online stores platforms such as eBay.com and Bonanzo.com, and then shipped by post to individuals and wholesale buyers. The products sold included counterfeit and misbranded male-enhancement pills, some of which contained drugs that the consumers were not aware of and could cause danger to their health, including heart attacks or strokes. If indicted, the defendants were facing a forfeiture allegation of USD 3.7 million, six properties or homes, two bank accounts, one Pay Pal account, and three certificates of deposit plus a maximum possible sentence of 30 years' imprisonment for the conspiracy charges, 10 years for trafficking counterfeit goods, and 3 years for introducing and receiving misbranded products in interstate commerce. One of the defendants also faced up to 20 years in prison for international money laundering and 20 years for smuggling.
- In July and August 2017 and March and June 2018, five individuals involved in a scheme to traffic steroids were sentenced in the United States.⁸ From approximately May 2015 until April 2017, the conspirators involved in the scheme manufactured steroid products made from raw materials that they purchased overseas and marketed as Onyx steroids using Onyx labels that were also ordered from overseas suppliers. The defendants sold the steroids to customers across the United States using email and social media platforms, collected payment through money remitters, such as Western Union and MoneyGram, and used false identifications and multiple remitter locations to pick up the proceeds. Some of the defendants laundered proceeds from the steroid sales through a tanning business, which they owned and operated specifically to launder the proceeds of the steroid operation.

- In April 2018, an individual was sentenced to 36 months' imprisonment for conspiring to distribute counterfeit, misbranded, and adulterated Botox into the United States. The individual concerned owned and operated a sophisticated wholesale drug distribution business involving individuals in Canada, Panama and Turkey. The Botox was sourced from Turkey and shipped to doctors in the United States. The drugs were adulterated because they were not kept at required constant cold temperatures, and sometimes the drugs were shipped and stored with no refrigeration or insulation. Further, some of the Botox had counterfeit exterior packaging, and the manufacturing lot numbers on the exterior of the drugs' cartons did not match the lot numbers on the drug vials inside the cartons.
- In March 2017, an individual pleaded guilty in the United States to engaging in a conspiracy to manufacture counterfeit Xanax pills and to launder the proceeds gained by the illegal scheme.⁹ The parties involved used imported equipment and components to support their operations. The two counts to which he pleaded guilty were subject to sentences of 5 years and 10 years.

In February 2016, a Pakistani national appeared in court after being extradited to the United States to answer charges related to the illegal importation and sale of misbranded and unapproved drugs, some of which were further alleged to have been counterfeit or controlled substances, and all of which were manufactured overseas and shipped to the United States.¹⁰ The company involved claimed to be, among other things, a leading and long-standing exporter of branded and generic pharmaceutical drugs and surgical products. The illegal drugs imported by the defendants included counterfeit or unapproved versions of Viagra, Lorazepam, Alprazolam, Diazepam, Zolpidem, and Phentermine. The defendants filled US drug orders by procuring brand name and generic drugs that they knew to be unapproved for the US market by the FDA from suppliers whose drug manufacturing facilities were not approved by the FDA and whose packaging and patient literature for their drugs were also not approved by the FDA. As part of the conspiracy, the defendants, using a series of email addresses, would forward the drug orders to a network of drug suppliers in Pakistan, India, the United Kingdom, and the People's Republic of China. To evade detection by customs authorities the drugs were concealed, in loose format, in plastic vitamin bottles and plastic water bottles. They would also use customs declarations that inaccurately or misleadingly described the contents of the shipments, or would not use customs declarations altogether. The drugs would often be shipped in mail parcels without packaging, without labels, and without patient safety leaflets or other written instructions and information. Penalties for these offences range from not more than 3 years in federal prison per count, to not more than 20 years in federal prison, per count. Each count also carries a penalty of up to USD 250 000.

Notes

¹ ASOP Global consolidated research collected over a number of years <https://buysaferx.pharmacy/for-the-media/examples-of-people-harmed-by-medications-bought-online/>

² Banned slimming drug kills medical student: Coroner attacks online dealers who target the vulnerable” The Daily Mail, United Kingdom (April 22, 2013); available at <http://www.dailymail.co.uk/health/article-2312986/Sarah-Houston-Banned-slimming-drug-DNP-kills-medical-student-coroner-attacks-online-dealers-target-vulnerable.html>. This medicine was misused. The patient took both anti-depressants and a pill marketed as a weight loss aid containing lethal ingredient.

³ At the manufacturing and wholesale levels.

⁴ Commission Staff Working Document SWD(2015) 189 final https://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2015/swd_2015_0189_en.pdf

⁵ See www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/april-23-2019-six-indicted-drug-conspiracy-included-production-and-distribution-powerful-synthetic.

⁶ See www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/january-18-2019-medical-company-executive-sentenced-smuggling-18-million-misbranded-pharmaceuticals.

⁷ See www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/march-8-2018-four-individuals-indicted-trafficking-counterfeit-goods.

⁸ See www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/june-20-2018-fitchburg-woman-and-saugus-man-sentenced-roles-counterfeit-steroid-conspiracy; www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/march-30-2018-lynn-man-sentenced-over-10-years-prison-role-counterfeit-steroid-conspiracy; www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/july-17-2017-gloucester-woman-pleads-guilty-her-role-counterfeit-steroid-trafficking-scheme; www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/august-28-2017-shrewsbury-man-pleads-guilty-operating-counterfeit-steroid-scheme.

⁹ See www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/march-28-2017-oakland-man-pleads-guilty-role-conspiracy-manufacture-counterfeit-drugs.

¹⁰ See www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/february-1-2016-pakistani-man-makes-appearance-us-district-court-denver-following-indictment-and.

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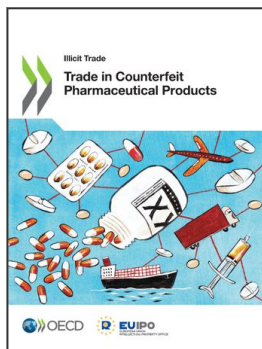
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