

Counterfeit Pharmaceuticals in Canada



The counterfeit criminal market in Canada

Counterfeit goods can be categorized into industry sectors: entertainment and software; clothing and accessories; industrial; and, food and pharmaceuticals. Counterfeits from all sectors have been detected, to varying degrees, across Canada. The industry sectors most commonly counterfeited in Canada are entertainment and software, and clothing and accessories (ex. CDs, DVDs or brand-name clothing).

As in other countries, some consumers in Canada knowingly purchase counterfeit goods. Other Canadian consumers unknowingly purchase a variety of counterfeit goods that are passed off as legitimate products. Counterfeit goods are sold at a wide variety of venues in Canada, ranging from flea markets and strip malls to large, well-known, retail outlet stores. Some counterfeits are concealed within legitimate goods while others are more obviously fraudulent.

The probability of consumers unknowingly purchasing counterfeits remains relatively low. However, the variety of businesses selling counterfeits remains a concern to law enforcement. Addressing the counterfeit criminal market is complicated by the varying levels of societal tolerance toward counterfeit goods in Canada.

Defining counterfeit pharmaceuticals

According to the World Health Organization (WHO), counterfeit pharmaceuticals are medicines, both

brand name and generic, which are deliberately and fraudulently mislabeled with respect to identity and/or source.

Counterfeits may be produced with the correct medicinal ingredients, or those medicinal ingredients may be in insufficient quantities or absent altogether. The medications may contain toxic or poisonous chemicals. The medication's appearance and its packaging may be visibly different (or inferior) from the genuine product. Or, the pharmaceutical packaging and the medication may be exactly replicated. In this case, laboratory testing of the drugs is required to identify fraudulent medication and then determine its chemical composition.

No country is immune from counterfeit drugs

The WHO estimates that 10% of medication globally is counterfeit. The criminal trade in counterfeit medication is more prevalent in developing countries with weak drug regulation, control and enforcement, and where basic medicines are scarce or irregularly supplied and unaffordable. The situation is endemic in southeast Asia and Africa, where the amount of counterfeit pharmaceuticals in circulation is over 50% in some countries. While the prevalence of counterfeit pharmaceuticals varies widely between developing and industrialized countries, there are increasing numbers of incidents of counterfeit medication globally. According to the WHO, in developing countries, the most counterfeited medicines are those used to counter both infectious and serious diseases, such as malaria, tuberculosis and HIV/AIDS, as well as basic infections.

New, expensive medicines such as hormones, corticosteroids, cancer drugs or anti-retrovirals¹ are the most frequently counterfeited medications in industrialized countries. Other commonly counterfeited types of drugs in industrialized countries are:

- lifestyle drugs which treat such conditions as sexual impotence, baldness or obesity, and
- psychotropic drugs which include opiate-based pain-killers, tranquillizers, stimulants and depressants.

Organized crime's involvement in counterfeit pharmaceuticals

Counterfeit pharmaceuticals, which historically were largely manufactured and distributed within many developing countries, have increasingly emerged in industrialized countries in recent years. Globally, organized crime groups are involved in the production and distribution of counterfeit or grey market² pharmaceuticals, using multiple countries as manufacture, transit and destination points. Several recent U.S.-led law enforcement projects demonstrate that organized counterfeit pharmaceutical operations traffic multiple types of controlled medications simultaneously. These criminal operations are highly profitable and typically involve numerous individuals and illegal

Internet pharmacies in multiple countries.

Medication is an attractive target for counterfeiting because the profits generated are high in relation to the volume of the ingredients needed for its production. Counterfeit pharmaceuticals are typically inexpensive to produce: non-medicinal or sub-potent ingredients can be substituted for the correct active medicinal ingredients. An additional public health concern is that criminal groups disregard regulatory standards for the production, distribution and storage of medication, greatly lessening the costs of illicit manufacturing.

The scope and magnitude of counterfeit pharmaceuticals in Canada remains relatively small in comparison to other industrialized countries. Currently, only a small number of criminal groups in Canada are involved in smuggling and manufacturing counterfeit medication.

Other Canadian criminal groups that have experience in the illicit synthetic drug market and have established smuggling routes domestically and internationally are well-placed to expand into the illicit importation, manufacture or distribution of counterfeit pharmaceuticals.

In one case of counterfeit medication smuggling in 2003, law enforcement seized 14.8 kg of counterfeit Viagra pills that were concealed within 118,100 cartons of counterfeit Canadian-brand cigarettes. This contraband was seized in three separate shipping containers that arrived at the Port of Vancouver from China. The counterfeit Viagra was worth an estimated \$1.1 million and contained approximately 74,000 doses.

¹ Corticosteroids (cortisone-like medicines) are used to relieve inflamed areas in conditions like severe allergies, skin problems, asthma, or arthritis. Anti-retroviral drugs are used to treat retroviruses, primarily HIV.

² In the "grey market," branded products have been diverted from the authorized distribution channel within a country or are imported into a country for sale without the consent or knowledge of the manufacturer.

In another incident in 2005, an airline pilot was sentenced to a one-year prison sentence for smuggling into Toronto 120,000 counterfeit Viagra, Cialis and Levitra pills, all of which are used to treat erectile dysfunction. The total value of the pills was estimated to be between \$366,000 and \$2,440,000, depending on whether the pills were intended to be trafficked in bulk amounts or in individual doses.

Counterfeit pharmaceuticals in Canadian pharmacies

Counterfeit drugs within licensed pharmacies in Canada are a rare occurrence. Despite stringent safeguards, criminally inclined individuals will identify vulnerabilities.

In 2005, counterfeit pharmaceuticals were found in two Ontario pharmacies – the first such cases within the country's licensed pharmaceutical system. The cases were unconnected, and in each case members of the pharmacy staff were charged with knowingly selling counterfeit medication. The seized drugs contained no active medicinal ingredients, the wrong medicinal ingredients or were grey market drugs.

In the first case, law enforcement seized grey-market Norvasc pills that are used in the treatment of hypertension and angina. As eleven patients of the pharmacy who were prescribed Norvasc died, the Ontario Coroner's Officer conducted an investigation into their deaths to determine if the counterfeit medication was a contributing factor. In January 2006, the Coroner's Office determined that in four of the eleven deaths, the manner of death was "undetermined" and the medical cause of death included "possible unauthorized medication substitution."

In the second case, law enforcement seized both shipments of counterfeit Viagra tablets and bulk chemical ingredients to manufacture Viagra pills. The pharmacist is alleged to have sold counterfeit Viagra from the pharmacy as well as through the pharmacy's website.

Illegal Internet pharmacies

Licensed Internet pharmacies provide accessible, convenient and private service to consumers. However, there are also illegal Internet pharmacies that typically sell a variety of medications that can pose health and safety risks, including:

- unapproved drugs,
- legal prescription drugs dispensed without a valid prescription,
- products that are marketed with fraudulent health claims, or
- counterfeit or grey market pharmaceuticals.

Illegal Internet pharmacies remain a concern to law enforcement and health agencies. These businesses operate without any authorized doctor/patient relationship. In addition, consumers receive medication of uncertain provenance and authenticity without information on correct use, dosages, drug interactions or side effects.

As with other websites that operate illicitly, it is difficult to track and examine the activity and merchandise of illegal Internet pharmacies. These sites open and close easily, frequently change their names and may operate from servers based in other countries. As law enforcement in both the U.S. and Canada have observed, some illegal Internet pharmacies mimic the appearance of licensed sites or

disguise themselves as originating from Canada to take advantage of U.S. consumers seeking Canadian pharmaceuticals. Therefore, consumers may have difficulty discerning between legitimate and illegal sites.

Some Canadians use illegal Internet pharmacies to obtain a variety of drugs for which they do not have a prescription and wish to purchase in relative anonymity. The illegal websites also supply some Canadians abusing or addicted to prescription drugs or seeking experimental or unapproved medications.

Negative effects of counterfeit pharmaceuticals

Counterfeit medicines can result in unexpected side effects, incorrect dosages, dangerous drug interactions, allergic reactions or the worsening of medical conditions. According to the World Health Organization, thousands of people around the world are injured or killed by counterfeit pharmaceuticals annually.

Substandard antibiotics that do not effectively treat bacterial infections result in antibiotic resistance causing infections that are difficult to treat, spread rapidly and are more virulent. Counterfeit medications have contributed to antibiotic-resistant forms of shigella, cholera, salmonella³ and tuberculosis. These serious diseases have endangered the lives of millions of people suffering from malaria and HIV/AIDS.

³ Shigellosis, (or bacillary dysentery), Salmonellosis and Cholera are bacteria infections of the intestine that cause diarrheal illness. Food and water contamination are often the cause.

Patients may have multiple chronic or serious underlying medical conditions. As a result, it can be extremely difficult to link counterfeit drugs directly as a contributing factor to injuries or deaths.

Consistent estimates of economic losses to the pharmaceutical industry are difficult to quantify. Most estimates range in the billions annually for global losses.

Counterfeiting may also result in patients' loss of confidence in the public health system and pharmaceutical industry. It can threaten the reputation of pharmaceutical companies.

Looking to the future

Canada has a standardized, highly regulated pharmaceutical and public health care system that is largely affordable to most Canadians. This significantly lessens any potential market for illegitimate supplies of pharmaceuticals in Canada.

The two incidents of counterfeit pharmaceuticals seized within Canadian pharmacies indicate that licensed pharmacies remain vulnerable to the infiltration of counterfeit medication, particularly when facilitated by corrupted pharmacy staff. However, the probability of counterfeit drugs within licensed pharmacies will remain limited.

In Canada, the individuals most at risk of encountering counterfeit pharmaceuticals will be those who seek psychotropic or lifestyle drugs (for which they do not have a prescription) from less than reputable sources. Other individuals at risk will be those who mix licit and illicit drugs or take multiple prescription drugs for non-medicinal uses.

Medication trafficked by criminal groups or sold by illegal Internet pharmacies is clearly more likely to be counterfeit than medication received from licensed sources. Given the multitude of websites selling pharmaceuticals of questionable provenance and authenticity, illegal Internet pharmacies provide the most likely vehicle for counterfeit drugs. However, incidents of counterfeit pharmaceuticals obtained from these sources (or resulting adverse health affects) will remain largely under-reported by victims.

Multiple criminal groups in Canada will remain involved in smuggling counterfeit medication into Canada, as well as illicitly manufacturing pharmaceuticals domestically. Distribution of this medication will continue within Canada with some smuggling to the U.S. occurring.

Counterfeit medication in Canada will remain a key concern to law enforcement and health agencies. The CISC network of law enforcement agencies will continue to assess the threat of counterfeit pharmaceuticals in Canada and target criminal groups involved in this activity.