



**GENERIC DRUGS
SAME QUALITY
BETTER PRICE**



CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

COUNTERFEIT MEDICINES

THE ISSUE

While counterfeit medicines are a rare occurrence in Canada, the counterfeit drug trade is on the rise both around the globe and on the Internet. Domestic and international measures to combat these illegal products must target the criminals engaged in counterfeiting without creating unintended consequences.

BACKGROUND

As defined by the World Health Organization (WHO), a counterfeit drug is:

"a medicine, which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."

Counterfeit medicines represent a serious public health concern. The use of counterfeit medicines can result in unexpected side effects, dangerous drug interactions, incorrect dosages, allergic reactions or the worsening of medical conditions.

According to drug regulators and law enforcement, the trade in counterfeit

medicines is on the rise, particularly on the Internet. Counterfeit medicines are generally found in developing and least developed countries, with estimates as high in some countries as 30% to 50% of the market. There has been a marked increase in counterfeit medicines in industrialized countries in recent years, but the incidence remains low (less than 1%). As Canada's Criminal Intelligence Service has observed, *"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."*

WHO's International Medical Products Anti-Counterfeiting Taskforce (IMPACT) has made a series of recommendations on how countries can deal with the problem of counterfeit medicines. These include stringent regulatory procedures, improved training for customs officers and quality control inspectors, improved policing, and increased public and health professional awareness. Patent enforcement was not regarded as an appropriate measure by IMPACT because counterfeit versions of both patented and non-patented medicines are produced by criminals. Counterfeit drugs are appropriately viewed as a public health issue in which organized or local criminals carry out counterfeit

activities, rather than a potential infringement of private rights.

In addition to the serious health risks these products pose, counterfeit medicines have the potential to divert business from legitimate generic and brand-name drug manufacturers whose products have received Health Canada approval for sale in Canada. Canada's generic pharmaceutical industry is also concerned about the international impacts of the counterfeit drug trade – while almost all generic drugs sold in Canada are made in Canada, 40% of generic manufacturer sales are generated through the export of Canadian-made pharmaceuticals to more than 120 countries.

CGPA POSITION

The CGPA supports the continuing efforts of Canadian health and law enforcement agencies to keep counterfeit drugs out of the hands of unsuspecting Canadian consumers. While counterfeit medicines represent a public health concern across jurisdictions, the domestic prevalence of these products is low. As such, it is imperative that any additional domestic measures to combat these illegal products involve strengthening existing regulatory controls and appropriately targeting the criminals engaged in counterfeit activities – without creating unintended consequences.