



## New Book is Essential Reading for Pharmaceutical Companies

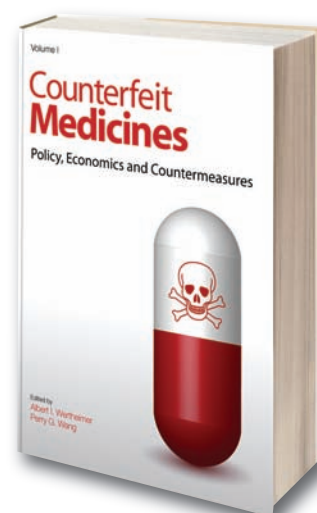
### Counterfeit Medicines, Volume I: Policy, Economics and Countermeasures

Although there is some debate about the extent of counterfeits in the world's pharmaceutical supply chain, it is undeniable that counterfeit and substandard medicines are a growing and dangerous business. They can cause major moral, reputational and financial damage to pharmaceutical manufacturers, as well as untold harm to patients who are deceived by the fake version of their medication. This book provides a concise account of the history, policy and law, and financial and economic aspects surrounding pharmaceutical product counterfeiting, as well as some of the countermeasures available to organisations.

This valuable publication discusses the problems experienced in lesser developed countries, and reports the activities and findings of governments and agencies around the world. The safety concerns regarding illicit online pharmacies are reviewed and an overview is given of the regulatory efforts attempting to stem their negative effects. The book provides important information on creating an overall anti-counterfeit strategy and a review of current countermeasures, including authentication and tracing programmes. In addition, the book compares some of the problems experienced with those encountered by other product areas in relation to counterfeiting, including fine art, wine, diamonds, currency and aeroplane parts. With the inclusion of economic and financial models and projections as well as real-life case studies, this book is essential reading for individuals and organisations affected by this complex issue.

*Volume II will cover detection, identification and analysis of counterfeit medicines and will be published near the end of 2012 (ISBN: 978-1-906799-18-2)*

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### From the Foreword by Peggy E. Chaudhry, Associate Professor of International Business, Villanova School of Business, USA

The Pharmaceutical Security Institute (PSI) reveals a clear trend in the growing number of fake pharmaceutical incidents (2054 in 2010 versus 196 in 2002) that involve customs seizures or police/health inspector raids and the increasing commercial size of these seizures. The United States Customs and Border Protection (CBP) and the United States Immigration and Customs Enforcement (ICE) now provide separate data on 'Consumer Safety and Critical Technologies', which highlights seizure data in areas that involve a potential risk to the consumer, such as fake cigarettes. In 2011, the CBP and ICE reported that counterfeit pharmaceuticals represented 34% and 13% of the total domestic value of seizure data in this consumer safety category in 2009 and 2010 respectively. In 2010, the World Health Organisation (WHO) reported that spurious/falsely-labelled/falsified/counterfeit medicines were found in products ranging from treatments for life-threatening conditions to less expensive generic versions of painkillers.

Overall, the variety of expert advice offered in Counterfeit Medicines Volume I: Policy, Economics and Countermeasures makes it a timely publication. This book encompasses a comprehensive debate of a wide array of salient issues that include the history of this illicit trade, the present policy and law governing counterfeit medicines, both the financial and non-financial motivations for pirates, the global politics and myriad of agencies involved with curbing this problem and the overall need to cultivate anti-counterfeiting measures to fight the growth of fake medicines. The analyses in this volume stem from a myriad of experts in this area who suggest strategies to successfully tackle this seemingly daunting task. The views of the authorities in this book collectively solicit the input of both government and industry leaders alike to work together to help rid the world of this potentially massive public health threat.

The viewpoints in this volume clearly support that counterfeit pharmaceuticals are a dangerous global menace. Through transnational criminal networks, fakes make their way into the hands of patients in all countries, accounting for an estimated 10% of the medicines sold worldwide. While the distribution is higher in lesser developed countries, fakes make their way into the United States and Europe as well. The PSI estimates that the counterfeit pharmaceutical industry is worth a staggering \$75 billion a year but, at the same time, cautions the use of statistics to estimate the size of the market. While it is difficult to know the true extent of the problem in terms of data, a myriad of reports on counterfeit drugs reveal that fake pharmaceuticals is clearly a problem that is growing. For example, in our work at the Villanova School of Business in Philadelphia, US, to establish a consumer complicity index for counterfeits, an internet survey was distributed to consumers in Brazil, Russia, India, China and the US to better understand their demand for illicit products. Overall, one-third of the 1910 total participants in these five countries' markets were willing to obtain, share or use a counterfeit product. We did anticipate high levels of complicity with fake movies in our study but what we found alarming was that, in some countries, over 25% of the consumers indicated an intention to be complicit with a fake pharmaceutical. The notion that consumers were receptive to acquiring a counterfeit pharmaceutical, giving it to a peer and/or using it for their own consumption, knowing that there was a health risk, was a disturbing outcome of our study. Furthermore, since our survey involved self-report of actual complicity with fake pharmaceuticals, we were not reporting the unknowing consumer using a counterfeit and our survey data could be under-representing illicit pharmaceutical consumption by 50% or more.

The collective work in this volume highlights that awareness campaigns must be employed to make the general public more cognisant of the dangers of counterfeit pharmaceuticals. For instance, the recent action of Pfizer and the National Association of Boards of Pharmacy to launch an education campaign to assist consumers to find legitimate online pharmacies through a website (<http://awarerx.org/>) and YouTube postings ([www.youtube.com/spotfakemeds](http://www.youtube.com/spotfakemeds)) is evidence of this type of anti-counterfeiting tactic.

With the advent of illegal online pharmacies, buying cheap drugs is easier than ever. With the rising cost of health care and an aging population, these alternative methods of acquiring medication may seem appealing. Consumers may not be aware that half of the drugs originating from these illegal online pharmacies are indeed counterfeit. Low-income individuals are especially susceptible to this fraud because they often pay medical expenses out-of-pocket and will look to the Internet for less expensive options and may not be aware of the potential dangers. In 2011, the Wall Street Journal in

its report on illegal online pharmacies estimated that one in six Americans has purchased medicines from this virtual distribution channel. In 2010, during the H1N1 scare, the United States Food and Drug Administration (FDA) warned against generic Tamiflu that was being sold on the Internet. Authorities purchased the drug without a prescription from a legitimate-looking website belonging to an illegal online pharmacy. The product did not contain the active ingredients of Tamiflu and instead contained an antibiotic similar to penicillin. It would have caused a potentially life-threatening reaction in those who are allergic to penicillin. Some of the experts in this book address recent US legislation, such as The Ryan Haight Act, designed to give both regulatory and enforcement measures for this virtual distribution channel. In addition, global initiatives to curb illegal online pharmacies, such as the International Internet Week of Action, are presented.

Counterfeiters simply copy or fake drug formulations and do not incur the costs of product development, making the prices they charge lower while still making a staggering profit. The work in this book clearly reveals the threats to legitimate pharmaceutical manufacturers and outlines the industry's concerns with piracy, which includes the potential damage to a company's reputation and financial position. A plethora of factors that entice the pirates to sell fake pharmaceuticals is discussed, which range from large profit incentives to the lack or absence of adequate drug regulation and penal sanctions to deter these illicit sellers. Several manufacturers have entered into their own investigations of fakes and this volume gives a detailed overview of how to evaluate a firm's exposure to both deceptive (where the fake product is a look-a-like of the genuine one) and non-deceptive (where a low price and poor quality signals a fake product) counterfeit pharmaceuticals. An array of countermeasures that ask probing questions about monitoring the company's supply chain and distribution channels is outlined in this book. In addition, a synopsis of overt, covert and forensic authentication methods is provided to debate technological 'track and trace' anti-counterfeiting measures.

Counterfeit pharmaceuticals are manufactured without regulatory oversight, so there is no way for the consumer to know their ingredients. The doses of active ingredients in these fakes may be low or non-existent, negating any potential therapeutic benefits. Even more disturbing is the fact that pirates may go further than a placebo effect and actually use harmful ingredients, such as highway paint and floor wax, in an effort to produce deceptive look-a-likes to the genuine product. On 13th March 2011, a 60 Minutes segment on 'The Difficult Fight Against Counterfeit Drugs' brought this dilemma to mainstream consumers and highlighted the crude packaging machines that were used in a house in Lima, Peru, to produce a significant number of fake prescription drugs that found their way into legitimate supply chains. The experts in this book suggest that collaboration between stakeholders is necessary for any progress in deterring the manufacture and distribution of counterfeit pharmaceuticals. The WHO's International Medical Products Anti-Counterfeiting Taskforce (IMPACT), established in 2006, has been active in forging these collaborations. Several authors address the efforts of IMPACT and other stakeholders, such as the FDA, the European Council in the European Union, the Partnership for Safe Medicines and the like, to coordinate the efforts of drug and regulatory agencies, governments, non-governmental organisations and pharmaceutical manufacturers.

#### The Editors of the Book

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