A Silent Epidemic: Protecting the Safety and Security of Pharmaceuticals

Threats to the safety and security of some of our most common pharmaceuticals are growing.

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Millions of people worldwide regularly buy medicines over the Internet, but how many of these transactions are genuine? Research carried out recently suggests that as many as 60% of online products could be counterfeit or substandard.

The dangers posed to supply chains by counterfeiting, parallel imports, diversion, and theft are growing globally, affecting not just the Internet but over-the-counter purchases, too. It's a silent epidemic that threatens consumer health and safety, forcing drug makers, retailers, and regulators to step up efforts to protect products.

SCALE OF THE PROBLEM

The current outbreak of H1N1 influenza and concern about the legitimacy of some antiviral drugs on the Internet has thrust drug safety into the spotlight once again. But it's an issue that affects all countries and impacts a huge range of products. A lack of reliable data makes it difficult, perhaps impossible, to quantify.

The problem is more exaggerated in developing countries, where the World Health Organization (WHO) estimates counterfeit medicines could account for up to 30% of sales. The estimate is about 1% in the United States and other developed countries. In 2007, about 3.5 million packs of counterfeit pharmaceuticals were confiscated at EU borders.

The problem is escalating and creating significant problems for manufacturers and consumers. Globalization, complex and lengthy supply chains, and grey markets like the Internet have created a boon for counterfeiters. The Internet, in particular, has been described as a "Trojan horse"—significantly increasing trade in counterfeit products as consumers take advantage of the discounts and greater discretion afforded by online purchases. Online pharmacies should be regulated just as retail pharmacies are, but they are far harder to police.


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Activities vary from fly-by-night operations to sophisticated factories capable of making medications and packaging that are visually difficult to distinguish from legitimate products. And counterfeiters have moved from making fakes with no active ingredients (placebos) to producing counterfeits with pharmaceutical activity—often because these counterfeiters are looking for repeat business.

Counterfeiting is not the only challenge presented to the pharmaceutical industry by the globalization of world trade. Globalization has resulted in a shift toward making APIs and finished products outside the developed world, creating issues with standards and quality control.

Closely linked to this is the issue of parallel imports, a legitimate concern in the EU. While parallel imports can help reduce medicine costs for consumers, they have significantly complicated the supply chain. Medicines frequently have to be repackaged by parallel importers, which can interfere with product integrity, potentially affect safety and quality, and bring about an increased risk of counterfeiting and piracy.

THE CONSEQUENCES

These developments pose serious risks to society. One of the most copied products is Viagra. Last year, Pfizer, maker of Viagra and other drugs, seized more than 11 million counterfeit tablets, capsules, and vials masquerading as trademarked goods. This year, German authorities uncovered a counterfeit-drug ring selling fake Viagra via Internet pharmacies. An investigation produced 46,000 counterfeit tablets.

Still, selling counterfeit and substandard drugs remains highly lucrative. In the developed world, expensive lifestyle drugs are copied most often. The opposite is true in developing countries, where counterfeiters target drugs that treat life-threatening conditions. Money made from counterfeit drugs hits manufacturers' incomes—damaging funding and investment into new drug development—

as well as hitting patients in the pocket and cutting tax revenues.

But more severe are the consequences for health and safety. Tamiflu, which has now taken over from Viagra as the spammers' product of choice, is a good example. The British Pharmaceutical Society has warned that anyone buying fake Tamiflu could end up with a product containing sugar or rat poison.

The consequences for consumer health can be extreme, leading in the most extreme cases to illness and fatalities. The WHO estimates that substandard medicines contribute to as many as 200,000 preventable deaths from Malaria every year around the world. Sadly, there are countless fatalities caused by the consumption of similar products, such as children suffering kidney failure after taking paracetamol syrup.

MOVING IN THE RIGHT DIRECTION

Unless more is done to protect original products and the supply chain through which they are transported and sold, the problem will grow. Clearly defined and effective strategies need to be put in place to protect brands, authenticate products, and ensure their integrity to consumers.

Thankfully, it's an issue that's high on the priority list of manufacturers, retailers, customs officials, and regulatory bodies, which are working together to put in place effective safety and anticounterfeiting strategies. But more still needs to be done, and vigilance is required.

Big strides have been made in techniques to improve product safety and security. Manufacturers now incorporate a range of track-and-trace features —such as bar codes—on their products to give each drug a unique code and allow it to be traced back through the supply chain to the original manufacturer. Web-based systems allow wholesalers, physicians, pharmacists, or patients to enter a code provided by the manufacturer to authenticate the product.

This is backed up by other overt and covert devices, such as packaging and labels. Identifiers such as holograms, color-shifting inks, codes, images, and dyes are used to create a multilayered barrier. Some are immediately visible to the naked eye while others must be checked using a microscope or special reader.

In the field, testing devices such as spectrometers and chemical assay kits are increasingly used to check and identify counterfeits or substandard products. A drug's fingerprint can be compared against standards for specific active ingredients, screening out bad products quickly and effectively. China is deploying a fleet of mobile forensic laboratories to examine medicines around the country.

Among the latest innovations are various seals that provide opening proof and act as a major tampering deterrent. A seal and protective wallet has been developed for Levitra that shows when the product is first opened. The coating used on the seal's adhesive will even destroy the cardboard packaging material if any attempt is made to remove the seal.

But technology alone is not enough. Legislatively, the U.S. Counterfeit Enforcement Act, which has just been introduced, is set to increase penalties for the sale of counterfeit and contraband drugs. Such developments will tighten up legislation and supply chains to protect drugs. The act includes several important recommendations including authorizing FDA to dictate that pharmaceuticals incorporate anticounterfeiting technologies; requiring manufacturers to alert FDA when one of its products may have been counterfeited; increasing penalties; and enhancing the tracking of drugs through the supply chain.

With FDA's Draft Guidance on In-Dose Taggants, FDA has issued draft guidance on incorporating physical-chemical identifiers into solid-oral dosage form drug products for anticounterfeiting. The agency is simplifying the process of incorporating taggants in an attempt to strengthen supply chain security.

Similarly, the proposed new EU Pharmaceutical Directive is to be welcomed along with other initiatives. The EU Directive is to make security seals and combined security features mandatory on every pharmaceutical pack sold in Europe. This is an important step in ensuring wholesalers and pharmacists are able to verify the authenticity of a product based on overt, covert or forensic means. On the negative side, it does not cover the Internet medicine market. More and more products will be purchased over the Internet and tighter regulation is needed.

Another key initiative from the EU is a new €210 million 'Citizen Protection' research fund, and to be covered under this fund is tackling counterfeit medicines and related criminal networks. This will be a collaborative research project involving at least three organizations in EU member states or accession countries.

These developments illustrate the growing international and political momentum to tackle the problem. The WHO has put in place an International Medical Products Anti-Counterfeiting Taskforce (IMPACT) focusing on anti-counterfeiting technology, harmonized legislation, tougher enforcement, and better regulation and public information.

Tackled collectively, this can be hugely effective. Nigeria is a good role model. Nearly a decade ago, Nigerian health authorities indicated that more than 60% of drugs in the country were fake or adulterated. But a vigorous anticounterfeiting campaign, including stiffer penalties, has reduced this number to 10–16%.

To differentiate between acceptable and counterfeit products is no easy-task. However, an effective strategy that incorporates a mix of authentication technologies backed up by political will and ammunition can have a big impact. The end result is a significant improvement in product safety and security. ■

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