

Lay down the law on fakes

Lax laws mean that drug counterfeiters often receive light punishments and companies can remain silent when they suspect bogus medicines in the supply chain. Winning the fight against fakes requires getting tough.

When it comes to counterfeits in the medicine cabinet, the danger is very real. Whether they contain harmful elements or no active ingredients whatsoever, they can make a sick person even sicker.

In countries such as Canada and the UK, authorities have linked isolated fatalities to the online purchase of medicines that contained high levels of dangerous metals or rat poison. Although the exact death toll from counterfeits in developing nations remains difficult to pinpoint with certainty, estimates run into the many thousands. One survey found that up to half of all doses of the malaria drug artesunate across Southeast Asia were fakes (*PLoS Med.* 5, e32, 2008).

Recent initiatives offer some hope that authorities finally understand the gravity of the counterfeiting problem. As the news special in this issue highlights, Interpol recently announced the creation of a special policing unit to tackle the problem, and pharmaceutical companies have launched public awareness campaigns. To really make headway, however, we need stronger rules that mandate the reporting of fake drugs and punish those who make them.

In many places, such as the US, the reporting of suspected counterfeit drugs is voluntary rather than mandatory. But numerous experts point out that in some cases pharmaceutical companies and suppliers might be reluctant to speak up about possible fakes on the market for fear of weakening consumer confidence in their product. In other words, a lack of obligatory reporting is likely to lead to underreporting.

Given the potential for counterfeits to cause harm, shouldn't companies be obliged by law to provide such information? One group of experts asked this very question, noting that in Britain suspected unapproved aircraft parts must be reported to the UK Civil Aviation Authority (*PLoS Med.* 2, e100, 2005). The authors of the piece call for industry, pharmacists, health workers and the government to be compelled to report suspected counterfeits much as doctors must currently alert authorities to cases of 'notifiable' infectious diseases.

In this day and age of rising drug prices and burgeoning online drug sales, products move swiftly to consumers at the click of a mouse. Alerting wide networks of online consumers that they have been scammed—or, worse, have bought pills laced with poison—can be difficult. So authorities desperately need prompt information to act swiftly and warn those in harm's way. To achieve this goal, the rules on counterfeits should change to ensure that health officials obtain any details

on suspect pills in the supply chain that drug makers or distributors are reluctant to divulge.

Law enforcement needs more information to catch counterfeiters, but they also need better rules to deter criminals. In 2004, US Food and Drug Administration experts lamented that penalties for creating phony medicines seemed weak, writing “for example, counterfeiting a trademark on a prescription-drug label is punishable by up to ten years in prison, whereas counterfeiting the drug itself is punishable by a maximum of three years in prison” (*N. Engl. J. Med.* 350, 1384–1386, 2004).

Legal changes on the horizon could put some teeth into enforcement. The US Counterfeit Drug Enforcement Act of 2009, proposed last June, would increase criminal fines and penalties for people who knowingly peddle counterfeit medicines (and also require legitimate drug manufacturers to report information about possible violations to authorities within 48 hours). Unfortunately, the bill has stalled in a congressional committee.

In 2008, the European Commission proposed changes that would toughen the law on falsified medicines. Those changes are currently pending final discussion and adoption by the European Parliament and Council of Ministers. Meanwhile, UK regulators have moved forward and proposed criminal sentences for counterfeiting in Britain—perpetrators would face up to 10–12 years in prison. As *Nature Medicine* went to press, the public consultation period on these rules was coming to a close.

It's worth noting that that some nations have a long way to go—as much as 30% of countries have little or no drug regulation at all, by World Health Organization estimates. And, in cases where a fake drug simply contained no active ingredient for a given indication, coroners cannot always determine that the victims would not have succumbed to the illness, anyhow.

Industry developers have come up with technological fixes to address the counterfeit conundrum, such as special marking on pill and boxes. But all of the holograms and bar codes in the world cannot stop the problem alone. Fake drugs threaten to undermine advances in medicine unless governments install tougher penalties and industry comes forth with more information. Drug makers themselves understand the risk of passivity. As Lilly Europe, a subsidiary of the pharmaceutical giant Eli Lilly, wrote in response to the UK's proposed new rules against counterfeiting in Britain, “the danger to the public lies in not acting.”