World agencies try to stem flood of fake drugs

Procrit, a drug to treat anemia, is replaced with bacteria-contaminated tap water. Nearly 200,000 bottles of Lipitor, an anti-cholesterol pill, are recalled after patients complain of a bitter taste. Vials of Neupogen, a medication given to cancer patients, are found to contain saline.

The sale of such counterfeit drugs has skyrocketed in recent years. In some countries, nearly 25% of drugs on the market are fraudulent, according to the World Health Organization (WHO). Counterfeit drugs make up an estimated 10% of the Southeast Asian market, and Chinese authorities say more than 50% of certain products in that nation are fake. In a WHO survey of seven African countries, 20–90% of antimalarial drugs there failed quality testing.

In the US, the Food and Drug Administration (FDA)'s investigations on counterfeit drugs have increased to more than 20 per year from an average of 5 in the late 1990s, according to an interim report filed by the agency in October 2003.

The FDA, the WHO and other public health and regulatory agencies around the world are taking initiatives to fight this growing problem. In November 2003, the WHO and the governments of Cambodia, China, Laos, Myanmar, Thailand and Vietnam announced they would work together to strengthen inspection and post-marketing surveillance of drugs. In those countries, the products imitated most often are antibiotics, and drugs used to treat tuberculosis, malaria and HIV/AIDS.

The WHO is also conducting workshops in many African countries to help drug manufacturers upgrade their standards and assist officials in improving drug screening and testing practices. "It takes a lot to battle the problem," says WHO spokesperson Daniella Bagozzi.

Pharmaceutical companies are taking their own steps to fight the problem. In December 2003, Johnson & Johnson and Pfizer—which manufactures Lipitor—told their wholesalers that they could only buy medicines directly from the company.

In the US, New York State congressman Steve Israel introduced legislation in October 2003 that would give the FDA the ability to recall counterfeit drugs and increase criminal penalties for counterfeiters.

Some nations are taking more extreme measures. In December 2003, the Indian government approved an amendment to its Drugs and Cosmetics Act, allowing lawmakers to seek the death penalty for people who manufacture or sell counterfeit drugs.

The FDA plans to take a multipronged approach to combat the problem. In its interim report, the agency recommends using authentication and track-and-trace technologies, implementing rapid-alert and -response systems, and increasing the awareness and education of health-care workers and consumers. Because the FDA does not regulate products bought from foreign countries through the Internet, the agency also suggests developing global standards for packaging, and international collaboration in law-enforcement efforts.

The FDA is also testing technologies such as radio-frequency chips, near-infrared spectroscopy and organic vapors to identify products. "The FDA is evaluating all available technologies," says agency spokesperson Jason Brodsky. "There is no single 'magic bullet' solution to stay ahead of the counterfeiters."

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For HIV vaccine trials, size does matter

When California-based VaxGen announced in February 2003 that its HIV vaccine selectively protects blacks from infection, experts questioned the statistical significance of the results. Out of the resulting controversy has emerged a real push to change the way minorities are recruited and retained in HIV vaccine trials.

"We have learned some important lessons from the AIDSVAX trial," says Peggy Johnston, director of AIDS vaccine research at the US National Institute of Allergy and Infectious Diseases. "We have to ... apply it to the future so we don't end up in this situation again."

In response to VaxGen's announcement, a US National Institutes of Health (NIH) working group reanalyzed the data and concluded that the protective effect observed in certain subgroups was a fluke. The group said the minority population in the trial was too small to detect any differences.

"The study population should mirror the people who are at the highest risk, and in the VaxGen trial, this simply was not the case," says Mark Feinberg, a professor of medicine at the Emory University School of Medicine. What's more, Feinberg says, VaxGen's claims actually make recruiting minorities for clinical trials more difficult.

"People from diverse racial and ethnic backgrounds are already skeptical of scientific researchers," he says. "The publicity generated by the AIDSVAX trial makes a complicated situation even worse."

Although the NIH set guidelines on minority participation in clinical trials in 1994, the numbers of women and people of diverse ethnic backgrounds in trials remain low. "This means that broad and deep community support will be needed, rather than a narrow focus on recruitment for a particular trial," says Steve Wakefield of the HIV Vaccine Trials Network (HVTN).

At a conference in September 2003, researchers renewed their commitment to making trials more representative of populations at risk. In October, the US sponsored a symposium on recruiting and retaining racial and ethnic minority participants in clinical trials.

As a result, the HVTN and the NIH are working closely with community leaders to engage local organizations, develop community education plans and build trust among minority populations.

"The challenge," says Wakefield, "is to turn all of this into realistic activity which addresses the legacies of mistrust in communities of color."

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