



# PATIENT SAFETY

---

## HIGHLIGHTS

---

Launched the Pfizer Medicine Safety Education Web site ([www.pfizer.com/medicinesafety](http://www.pfizer.com/medicinesafety)), which works to bridge the gap in knowledge about how medicine safety is determined, monitored, and communicated to health care professionals, patients and journalists.

---

Continued to rigorously conduct reviews of all existing nonclinical safety data prior to testing a drug candidate for the first time in a human clinical trial.

---

Provided anti-counterfeiting training to enforcement agencies and continue to test products free of charge to determine their authenticity. Since the program's inception in 1998, training for authorities has been conducted in 79 countries.

---

Patient safety is a paramount concern for Pfizer from the moment a new compound is discovered, and for as long as a medicine is prescribed. It is our ethical and regulatory responsibility to monitor the safety of our medicines everywhere they are marketed. Once a drug compound is approved, we continue to monitor its safety and work with governments and others to secure the supply chain and prevent counterfeiting.

We are committed to broadening safety awareness and therefore strive to improve patient safety communications. We are also exploring mechanisms to improve communications between Pfizer and patients and health care professionals, when adverse effects are reported, so that we can aggregate data and respond appropriately. Pfizer employs more than 2,000 medicine safety specialists including research scientists, physicians, nurses, pharmacists, epidemiologists and others. These colleagues work with regulatory authorities to understand, as precisely as possible, the risks and benefits of our medicines before and after they are cleared by regulatory authorities. Our safety processes include collecting adverse event reports, conducting observational studies, and funding independent safety studies that are conducted by third-party investigators.

## Communicating Patient Safety Information

We encourage patients and caregivers to contact us or their doctors if someone has experienced any adverse effect that might be related to one of our medicines. Information about how to contact Pfizer is posted on our Web site and included in our medicine packaging.

Our new online tool, the *Medicine Safety Education Web site* ([www.pfizer.com/medicinesafety](http://www.pfizer.com/medicinesafety)), is designed to help U.S. health care providers, public health professionals, patients and caregivers learn more about medicine safety. It contains valuable information about how to report an adverse effect and how to contact both Pfizer and the Food and Drug Administration. Specific sections are also tailored for different audiences. For health care professionals, the site provides information on understanding risk and

working as partners with patients. For patients and caregivers, it provides tips for understanding the risks and benefits of medicines and for protecting their own safety.

## Adverse Event Reporting

Every medicine, even commonly used medications such as aspirin, carries the risk of adverse effects. Pfizer is committed to examining reported adverse incidents to identify and react appropriately to any safety concerns with our medicines.

To help speed the identification of potential safety concerns, Pfizer is a collaborator with Brigham and Women's Hospital, a teaching hospital of Harvard Medical School, in a study to improve digital reporting of adverse events. Using patient electronic medical records, doctors can report adverse events by indicating when patients have been taken off drugs, answer a few questions and submit the adverse event report. A third-party public/private liaison organization then sends these notifications to the FDA and to the pharmaceutical company. We hope that this study will help doctors more quickly and conveniently report any suspected adverse events, and help us and those who regulate us improve our ability to react more quickly and appropriately when safety concerns arise.

The study, which stopped collecting data in June 2009, demonstrated that it's possible to reduce the burden of reporting for doctors using electronic health records to the point where they will report certain types of adverse events at the point of care. This will mean companies like Pfizer, regulators and doctors will have the benefit of meaningful information about experiences with medicines across patient populations more quickly than is possible using existing paper-based systems.



## Safety in R&D

Throughout a medicine’s life cycle there are a number of risk and benefit assessments that take place. This work is carried out by a joint drug safety and clinical initiative of Pfizer Drug Safety Research & Development (DSRD), which has developed a consensus recommendation on the safety of clinical trials that will be first carried out in human subjects.

## Post-Marketing Studies

Although Pfizer’s clinical trials are always designed to uncover potential side effects and risks of medicines before they are introduced to the public, additional risks as well as benefits can become apparent after our drugs have been approved and are consumed by broader and larger populations. We acknowledge that our responsibility for the safety of our medicines does not end when they are approved, and we have committed substantial resources to information about the performance of our medicines after they have been publicly released. We are also committed to providing transparency about our post-marketing activities and continue to provide user-friendly, up-to-date information on our studies through our Web site.

→ READ MORE AT  
[WWW.PFIZER.COM/RESEARCH](http://WWW.PFIZER.COM/RESEARCH)

## Counterfeiting & Distribution

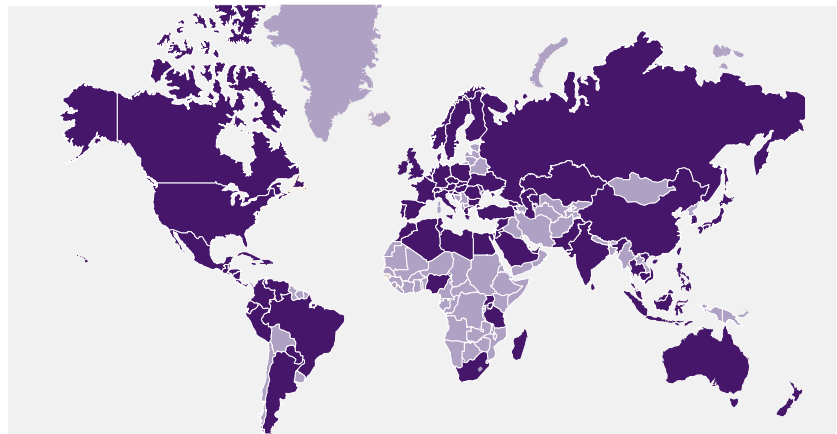
Pfizer has taken a leadership position among pharmaceutical companies with its commitment to protect consumers of our medicines from the dangers posed by counterfeits. Pharmaceutical counterfeiting is on the rise globally—the WHO estimates that while less than 1 percent of medicines in developed countries are counterfeit this increases to between 10 and 30 percent in developing countries. This risks the health of millions of patients who take for granted that their prescription medicines are both safe and effective. Counterfeit medicines often lack the active pharmaceutical ingredient of the authentic product, depriving patients of the expected therapeutic benefit. Worse yet, counterfeit medicines may include toxic materials.

Although the U.S. pharmaceutical distribution system is among the safest in the world, incidents of counterfeiting continue to increase. Of the approximately 45 million counterfeit tablets seized by authorities since 2004, 11.1 million were seized in 2008 alone, nearly 29 percent over 2007.

Pfizer has established business practices to secure the distribution system and has increased cooperation with law enforcement agencies to prosecute counterfeiters and promote public policies that reduce counterfeiting. For example, we provide training to enforcement agencies and test products free of charge to determine their authenticity. Since the program’s inception in 2008, training for authorities has been conducted in 79 countries. We have also made a considerable investment in Radio Frequency Identification Devices and other technologies to deter and detect counterfeiting operations. We will continue to protect the integrity of our products by partnering with wholesalers, pharmacists, regulators and law enforcement agencies around the world to advocate for more public investment in enforcement, and for stronger penalties for those found guilty of counterfeiting medicines.

### COUNTERFEIT PHARMACEUTICALS

As of June 2009, counterfeit products have been confirmed in at least 85 countries.



- Countries without confirmed counterfeit products
- Countries with confirmed counterfeit products

#### STAKEHOLDER COMMENTARY

“I consider Pfizer to be the global pharmaceutical industry leader in scientific excellence and corporate responsibility.

The company gives top priority to safe use of medicines and has integrated risk management concepts throughout the product life cycle. Having sought strategic advice from independent experts, Pfizer senior management proactively introduced a sound governance system throughout the organization. There are early indicators that this system is enabling Pfizer to make robust decisions with a focus on health and well-being of patients. Pfizer has taken early and effective actions, whenever needed, in order to minimize risks to patients. The company is now well placed to evaluate for positive impact of its actions and safety initiatives on public and individual health metrics. Pfizer has led the provision of general safety and risk management information directly to the public. They now plan to engage stakeholders more closely in the life cycle management of Pfizer medicines: another innovative first-in-industry initiative from Pfizer that should be highly commended.”

**DR. PANOS TSINTIS**

MEDICAL DIRECTOR, CHOICE PHARMA

## LOOKING FORWARD

Patient safety concerns will continue to be a priority for Pfizer. New drugs hold the promise of improving patients' lives and promoting healthy lifestyles. We seek to increase partnerships with government and enforcement agencies overseas to address safety concerns in the supply chain. We will also remain committed to transparency on safety issues and post-marketing research. As we improve our ability to identify and track adverse events, we will also need to improve our ability to communicate these concerns responsibly to patients and health care providers.