

The following statements have been provided should you be confronted with these contentious questions on the topic of medicine safety. Many of these points are generally not well received or trusted when communicated by someone from the pharmaceutical industry and so should only be used in response to the following questions.

Isn't everything you've told me about safety just a marketing tactic—surely all Pfizer is really focused on is profit?

- Inarguably, good safety is good business. Without the trust of doctors and patients, Pfizer could not succeed as the world's largest pharmaceutical company.
- Medicine safety is a priority for us on a personal level also. At the end of the day, we too are patients, and so are our families, children and friends.

Why doesn't Pfizer report all safety issues as soon as they arise? Shouldn't patients be made aware of potential risks as soon as possible?

- Communicating possible risks prematurely can have serious consequences if, as a result, patients stop taking the medicine they need. Pfizer, along with regulatory authorities, thoroughly investigates reports of unexpected adverse events to assess the reasons for the event, and then communicates findings to physicians, patients, and regulators in the most timely and responsible way possible.

Why do some medicines remain on the market even after safety risks are identified?

- Medicines as well as other medical treatments such as surgery, radiation therapy and medical devices have benefits and risks. Even common activities such as driving a car, flying on an airplane or crossing a street have benefits and risks.
- The FDA will approve a medicine for marketing only when its benefits outweigh the risks for its intended use.
- Our primary goal is to ensure that patients who will benefit from the medicine are able to do so, with equal consideration given to making sure both physicians and patients understand everything that is known about the risks—so that they can decide together whether a particular medicine is the best treatment option.



www.pfizer.com/medicinesafety



SAFETY FACTS

POCKET CONVERSATION GUIDE

*Updated January 2009.
Intended for U.S. audiences.*

www.pfizer.com/medicinesafety



1

Patient health is a top priority at Pfizer, and we are dedicated to ensuring our medications are as safe and effective as possible.

- Pfizer will spend billions of dollars this year on research and development. That investment is designed to answer two fundamental questions about the potential medicines we study: Are they safe, and do they help patients?
- Ninety-nine percent of the new medical entities that are tested fail to make it through our own development process; many because they do not meet our rigorous standards for human safety.

2

From a medical compound's discovery, through its development and for as long it is prescribed, all of our medicines undergo thorough safety monitoring and evaluation in coordination with health authorities around the world.

- We are continuously monitored by regulatory authorities through practices such as unannounced inspections of our patient safety data collection and reporting processes.
- We also engage outside physician advisory panels to work with us to ensure patient safety.
- Pfizer has a team of more than 2,000 colleagues, including medical research scientists, doctors, nurses and pharmacists, dedicated to our medicine safety operation. The primary responsibility of these colleagues is identifying, analyzing and reporting potential safety issues at every point in the life of a medicine.

- We know more now than ever before about the safety profiles of our medicines. This is a result of enhanced safety studies, improved methods of gathering information about patient experiences and strengthened regulatory requirements.
- Our drug safety system is designed to continuously gather and analyze information about patient experiences with our products. Staff scientists and physicians actively review on a routine basis patient safety experiences with our medicines. We use sophisticated techniques, computer analytics and clinical judgment to determine the possibility of a new risk once a drug is on the market.

3

Our approach is to err on the side of caution in reporting and monitoring safety issues. We work with physicians and outside medical experts to ensure that all potential safety concerns are thoroughly evaluated and risks are communicated to patients in the most timely and responsible way possible.

- Because additional risks or benefits can become apparent after a medicine reaches a broader patient population, regulators are increasingly focused on post-approval safety surveillance.
- Regulators require plans to monitor patient safety post-approval. As part of our commitment to medicine safety, Pfizer proactively designs and proposes post-approval safety studies as an integral part of our applications for new drug approvals. In addition, we prepare REMS (Risk Evaluation and Mitigation Strategy)—a strategy to manage a known or potential serious risk associated with a drug or biological

product, required by FDA when determined necessary, to ensure that the benefits of the drug or biological product outweigh the risks of the product, when appropriate.

- Working with regulators and independent investigators, we have currently invested hundreds of millions of dollars in scores of long-term studies of over 50,000 patients in real world clinical practice environments.
- We submit detailed risk management plans to regulatory authorities for all of our new filings in the U.S. and EU. These documents provide detailed strategies for evaluating potential health risk signals after a drug is marketed.
- Regulatory guidelines provide a check and balance system for safety reporting. Pfizer must notify the FDA of adverse event reports within seven days of becoming aware of an unexpected life-threatening safety issue; within fifteen days for a serious unexpected health risk; non-serious events are aggregated and reported periodically.

4

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

- A new online tool, the Medicine Safety Education Website (www.pfizer.com/medicinesafety) contains valuable information about how to report a side effect displayed on every page of the website content, including Pfizer's toll-free number (1-800-438-1985) and a link to the FDA's MedWatch website.

- Pfizer scientists work to detect health risks as early in a medicine's life-cycle as scientifically possible, using information reported by physicians, patients and caregivers, as well as peer-reviewed journals and medical literature. Working with health authorities, we use this information to help more accurately communicate benefits and risks of our medicines.

5

We continuously work to broaden safety awareness and improve our safety communications. These include:

- Supporting the development of innovative education methods and tools about medicines and patient health, including our Medicine Safety Education Website (www.pfizer.com/medicinesafety);
- Making information on our medicines' labeling and in all communications to patients and their doctors easier to understand;
- Engaging in public-private partnerships to develop innovative patient safety reporting and analysis systems;
- Developing, and continually updating, information for doctors and patients that explains appropriate use of our products;
- Producing training videos and brochures for physicians, including those who conduct clinical trials;
- Incorporating clearer safety information on our product literature, including on our websites (www.pfizer.com/medicinesafety) and advertisements;
- Engaging in an ongoing dialogue with the public, physicians, legislators and journalists about how medicine safety is monitored and the role of the pharmaceutical industry.