



# Patient & Product Safety Policy



Pacira BioSciences, Inc. (“Pacira” or the “Company”) is committed to never putting a patient in harm’s way.

## **Putting Patient Safety First in Clinical Research**

Our clinical trials are conducted in conformance with Good Clinical Practice guidelines as defined by the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Any employees or third parties involved in clinical trials sponsored by Pacira are trained to follow Good Clinical Practices. An independent ethics committee reviews and approves proposed Research & Development protocols before any clinical trial may begin. Our risk management framework helps us monitor any potential risks to our high quality and safety standards. Potential risks may be identified through audits of our sponsored clinical trials—both internally and of our external partners.

## **Ensuring Quality in Manufacturing Supply**

We are committed to upholding all applicable regulations and best practices through rigorous quality control and quality assurance protocols. All products at Pacira are manufactured in accordance with current Good Manufacturing Practice (cGMP) regulations enforced by the U.S. Food and Drug Administration as overseen by our quality management team.

In addition to our own internal quality controls, requirements for our suppliers have been designed to assure a consistent production process that prioritizes patient safety and high quality standards. This comprehensive approach to patient safety and quality control allows us to deliver our products safely and effectively.

## **Combating Risks from Counterfeit Products**

Pacira is committed to minimizing the threat of counterfeiting to ensure that patients receive authentic versions of our products. We are committed to abide by all applicable safety protocols and regulations mandated by the Drug Supply Chain Security Act, which outlines a process to achieve electronic tracing of the packaging of our products and to ensure proper distribution to health care providers in the U.S. All Pacira products contain unique serialization numbers and electronic tracking capabilities for internal, external, and regulatory tracing purposes.

One way U.S. consumers could be exposed to potential counterfeit drugs and medical devices is through illegal online sales. Pacira does not currently distribute its products through online pharmacies. Moreover, Pacira sells and delivers all of its products directly to health care professionals through a “closed” distribution system, which further minimizes the risk of counterfeiting.

In addition to the electronic tracking features in all of our packaging, Pacira products contain certain safety features, such as anti-tampering components and standardized labels, that are easily recognizable to any health care professional who has been trained to use our products. We are committed to cooperating with all appropriate federal, state, local, and any other regulatory agencies to identify, report, and minimize the production of any counterfeit items that may be mistaken for genuine Pacira products.

## Pharmacovigilance

Pacira is committed to monitoring the safety of its products and to ensure that we implement high, internationally recognized standards for good pharmacovigilance practices. It is our policy to:

- Comply with all applicable legal and worldwide regulatory requirements for handling safety information and product complaints.
- Continually monitor safety information and product complaints regarding the use of our marketed or investigational products and take appropriate actions to minimize risk to patients.
- Communicate important safety findings to clinical investigators, health care professionals and regulatory agencies in a timely manner.

All Pacira employees, partners, suppliers, contractors, vendors, and consultants are required to report any safety information and/or product complaints they receive to the Company, as well as complete training on obligations to report safety information in their respective roles in service to our company.

