

Report an Adverse Event or Product Complaint

Report adverse events, product complaints, and counterfeiting or tampering

Lilly is committed to meeting our patients' expectations to receive safe, high-quality medicines. All employees and contract workers on assignment at Lilly are required to report the following information to the designated Lilly contact. If you are in doubt about whether to report a safety concern, please make a report.

WHAT TO REPORT

Adverse Events:

- Any undesirable medical occurrence in a patient administered a Lilly product (drug or device), including side effects already listed in the package insert
- Any observation in animals or humans that is unfavorable and unintended and that occurs after any use of an Elanco product

Product Complaints: A customer's written, oral, or electronic communication that alleges deficiencies related to the identity, quality, purity, durability, reliability, safety, effectiveness, or performance of a distributed drug product, drug/device combination product, medical device, radiopharmaceutical, animal health premix, API (active pharmaceutical ingredient), process intermediate, or fermentation product.

Suspected Counterfeiting or Tampering:

- *Counterfeiting:* A counterfeit medicine is one that is deliberately or fraudulently mislabeled with respect to identity and/or source. A counterfeit drug, container, or label bears the trademark, trade name, or other identifying mark (e.g., shape or color), imprint, or device of a drug manufacturer, processor, packer, or distributor without requisite authorization and with the intent to mislead purchasers into believing the product is authentic
- *Tampering:* The manipulation of any authentic product or packaging thereby rendering it false or misleading, with malicious or illegal intent

WHEN TO REPORT

Any event involving a known or suspected human death, counterfeiting, or tampering related to a human or animal health product or device must be reported immediately (within 24 hours of receipt). All other reports, whether they relate to humans or animals, must be made within one business day.

HOW TO REPORT

Employees and contract workers on assignment at Lilly, in certain functional groups or organizations (e.g., sales, field-based medical) who have a higher likelihood of receiving adverse event or product complaint reports directly from customers are provided additional training and may have additional reporting requirements. Requirements for reporting adverse events from clinical trials are specified in the trial protocols.

Report an Adverse Event or Product Complaint

How to Report Issues Relating to Human Health Products and Devices

In the United States:

- Any known or suspected death, counterfeiting, or tampering must be reported immediately **(within 24 hours of receipt)** by calling The Lilly Answers Center (TLAC), 1.800.LillyRx (1.800.545.5979).
- Any other adverse event or product complaint must be reported **within one business day** by calling The Lilly Answers Center (TLAC), 1.800.LillyRx (1.800.545.5979) OR by using an alternative reporting method approved for a particular Lilly component.
- For more information on reporting in the U.S., see the [U.S. Policy on Adverse Events and Products Complaints](#).

Internationally:

- To report an adverse event, contact the responsible product safety (pharmacovigilance) representative according to the local Lilly process
- For product complaints or known or suspected counterfeiting or tampering, contact the responsible complaint person the local Lilly affiliate according to the local process.

How to Report Issues Relating to Elanco Animal Health Products

In the United States:

To make reports related to Elanco Products, including any reports of known or suspected human death, call the Elanco phone line at 1.800.428.4441 or 1.888.545.5973.

Internationally:

To make reports related to Elanco products, including any reports of known or suspected human death, contact the local or regional Elanco product safety (regulatory or pharmacovigilance) representative as designated in local procedures.