

1. Scope

Applicable to all Amgen staff members, consultants, contract workers, and temporary staff worldwide ("Covered Persons"). Consultants, contract workers, and temporary staff are not Amgen employees, and nothing in this Policy should be construed to the contrary.

2. Policy

Prompt and accurate reporting of Adverse Events is critical to protecting the health and safety of patients who use Amgen's products around the world. An Adverse Event is defined as any undesirable medical experience or change in an existing condition which occurs during or after use of any marketed or investigational product. For purposes of this policy, Adverse Events include medication errors, administration overdose, and product misuse/abuse and should be reported. An Adverse Event should be reported whether or not considered causally related to the product.

It is Amgen's policy to ensure comprehensive international collection, review and reporting of all Adverse Event information associated with the use of Amgen's investigational or marketed products; to support understanding of Amgen products' safety profiles; and to ensure full compliance with all laws and regulations related to product safety.

All Covered Persons must:

- Report to Amgen Global Safety or a local Amgen subsidiary within one business day any Adverse Event that they become aware of, at any time, including during non-working hours (e.g., while on vacation), that occurs in conjunction with Amgen product administration

Note: The requirement to report does not apply to Adverse Events that are addressed by any systematic data collection program ongoing at Amgen. These programs incorporate formal safety data collection processes and may include clinical trials, post-approval marketing studies, patient programs, disease management programs, or surveys of patients or healthcare providers. If a Covered Person does not know whether an Adverse Event is reportable through an existing Amgen systematic data collection program, then he/she must report the Adverse Event pursuant to this Policy. Procedures for collection of Adverse Event information are documented in the protocol, program process documents, or charters of these programs.

How to Report an Adverse Event

- Information on Adverse Events must be directed to a local Amgen office for subsequent forwarding to a regional safety hub. Contact numbers for local offices are posted on the Amgen Web site. Alternatively, Covered Persons may contact corporate headquarters using the following contact numbers:

Amgen Global Safety, Thousand Oaks

Phone: 805-447-3505 or 1-800-772-6436 (1-800-77-Amgen)

Fax: 888-814-8653

- Covered Persons should attempt to obtain details that will assist Global Safety in its follow-up, e.g., patient initials or name, a description of the Adverse Event, the Amgen product in use, and patient or reporter contact details.
- Information about Adverse Events must be kept confidential. Covered Persons should not discuss any information concerning an Adverse Event report with anyone except the reporting person or entity, supervising staff, staff in Global Safety, and the Law Department, unless otherwise directed.

3. Additional Information

Covered Persons Responsibility for Compliance

Every Covered Person worldwide is required to follow (1) the Amgen Code of Conduct, (2) all applicable laws and regulations, and (3) Amgen governance documents applicable to him or her, including without limitation, those relating to this Policy. Covered Persons should exert due diligence in preventing violations of such laws, regulations, and governance documents. Covered Persons must refer to the governance documents in effect for the geographic area in which they work, or for which they are responsible, or request guidance from their manager or compliance representative with responsibility for that geographic area. See Section 4, below, for a non-exhaustive list of governance documents related to this Policy. The term “governance documents” in this Policy means Amgen’s written policies, standards, procedures, business practices, and manuals.

Amgen expects its managers to (1) be familiar with (or take appropriate steps to become familiar with) the laws, regulations, and Amgen governance documents applicable to the activities they manage or supervise, (2) ensure their direct reports have appropriate training on compliance issues to perform their job functions, and (3) supervise their direct reports with respect to compliance requirements and activities.

If Amgen determines that any Amgen staff member has violated this Policy, applicable laws or regulations, or any governance documents, appropriate disciplinary measures will be taken, to the extent permitted by local laws. The following is a non-exhaustive list of possible disciplinary measures to which Amgen staff members may be subject (subject to local laws): oral or written warning; suspension; removal of job duties/responsibilities or demotion; reduction in compensation; and termination of employment.

Subject to local laws, Amgen reserves the right to take whatever disciplinary or other measure(s) it determines in its sole discretion to be appropriate in any particular situation, including disclosure of the wrongdoing to governmental authorities. Nothing in this Policy changes the at-will nature of employment at Amgen, its affiliates or subsidiaries, where applicable.