Amgen GLOBAL CORPORATE COMPLIANCE POLICY

ADVERSE EVENT AND PRODUCT COMPLAINT REPORTING

1. Scope

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

2. Policy

It is Amgen's policy to comply with all regulations and laws worldwide relating to Adverse Event or Experience (AE), Other Safety Finding (OSF), and Product Complaint (PC) reporting (collectively known as "Reportable Events"). All Covered Persons are responsible for reporting Reportable Events to the appropriate unit (see section 'How to Report' below) within one business day of learning of the Reportable Event. It is Amgen's mission to serve patients, and prompt and accurate reporting of Reportable Events is critical to protecting the health and safety of patients who use Amgen's products around the world. Amgen will train all Covered Persons on the requirements of this Policy annually.

Staff in managerial positions must supervise their direct reports with respect to compliance requirements and activities within this Policy.

It does not matter whether the Reportable Event is thought to be caused, or not thought to be caused, by taking an Amgen product – all AEs, OSFs and PCs must be reported. You must still report a Reportable Event even though it is listed in the approved company prescribing information as a possible side effect. In addition, Covered Persons may learn of Reportable Events during business transactions (e.g., a sales call) or non-business events (e.g., a social event) and all must be reported according to the requirements of this Policy.

Additionally, Covered Persons who engage with third-party vendors to conduct activities that may collect Reportable Events (e.g., market research, patient support programs and arrangements with specialty pharmacies) are responsible for ensuring, prior to initiation of the engaged service, that contracts contain appropriate language consistent with the requirements of relevant global standard operating procedures requiring the collection and reporting of Reportable Events to Amgen and that vendors are trained on these reporting requirements.

Furthermore, Covered Persons with a defined role and responsibility in patient or product-specific engagement activities, including, but not limited to, designing, initiating, executing and/or closing out of patient support programs, or engaging third-party vendors to perform any or all of such activities, must adhere to processes and systems described in relevant global standard operating procedures requiring the collection of Reportable Events (for example, *SOP-429209, Vendor Engagement of Safety Reporting Requirements for Commercial Programs).* Some examples of patient or product-specific activities are: provision of disease and product related information and resources; healthcare professional support (phone, chat, home delivery, etc,); financial assistance to include co-pay and reimbursement / compensation schemes; and social media, digital health device trackers and reminder programs.

This Policy does not apply to formal data collection processes, such as clinical trials or observational studies with formal protocols in place to collect, analyze, and report Reportable Events. If in doubt whether the Policy applies, Covered Persons should report Reportable Events.

What to report:

Term	Definition
Adverse Event or Adverse Experience (AE)	Any untoward medical occurrence in a patient administered an Amgen product and which is not necessarily caused by the Amgen product. An AE can therefore be any unfavorable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, combination product, or medical device, whether or not considered related to the product. This includes: ▪ any clinically significant worsening of a pre-existing condition; or ▪ an AE that has been associated with the discontinuation of the use of a product.
Other Safety Findings (OSF)	For the purposes of this Policy the following are considered Other Safety Findings regardless of whether they are associated with an AE and they must be reported to Amgen: ▪ Use of an Amgen product while pregnant and/or breast feeding. This includes pregnancies in women whose sexual partner took, or is taking, an Amgen product. ▪ Medication errors ▪ Overdose ▪ Underdose ▪ Misuse is defined as the intentional improper use of a medicinal product, combination product or medical device not in accordance with the authorized product information. ▪ Abuse ▪ Addiction ▪ Transmission of an infectious agent through a contaminated Amgen product ▪ Accidental Exposure ▪ Occupational Exposure ▪ Lack or loss of therapeutic efficacy ▪ Missed dose, if not taken prior to the next scheduled dose ▪ Unexpected therapeutic benefit

Term	Definition
	▪ Reports of patient "death" after exposure to Amgen's product where no other details are provided (e.g., fatal outcomes) ▪ Off-label use of an Amgen product defined as the intentional use of a product in a manner inconsistent with the locally approved label, i.e., a different dose, use, indication or patient population than that approved in the local label. U.S. Commercial field staff are not required to report off-label use unless the off-label use is associated with an AE. However, U.S. Commercial field staff must report all other AEs, PCs and OSFs irrespective of whether the event is from on-label or off-label use.
Product Complaint (PC)	Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a drug, combination product, or device after it is released for distribution to market or clinic by either: (1) Amgen or (2) distributors or partners for whom Amgen manufactures the material. This includes all components distributed with the drug, such as packaging, drug containers, delivery system, labelling, and inserts. Use Error is a situation in which the outcome of device use was different than intended, but not due to malfunction of the device. The error may have been due to a poorly designed device, or it may have been used in a situation that promoted incorrect usage. Use errors are considered product complaints.

When to Report

Your reporting obligations are met by directly submitting Reportable Events via ASRP or by calling the appropriate office within 1 business day.

Note: Reportable Events received (i.e., emails and voicemails) by a Covered Person when out of office or while on vacation/holiday must be reported within 1 business day from the date the Reportable Event was received by the Covered Person regardless if there was no one available to retrieve the Reportable Event. It is the responsibility of the Amgen staff member to set up an out of office message providing alternative contact details when away from the office for a prolonged period. It is best practice to utilize group email addresses when engaging with external reporters rather than providing individual contact details to ensure Amgen can act upon such reports when one person is away.

How to Report

- Report information on AEs, OSFs and PCs by contacting any of the following:
- Amgen Safety Reporting Portal (ASRP): https://amgensafetyportal.force.com/asrp
- Your local Amgen Medical Information/Safety office. Contact numbers for local Medical Information/Safety offices are posted on the **MyAmgen website**; or
- Corporate headquarters using the following contact numbers:

Amgen Medical Information/Global Patient Safety

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

Please note that for ASRP reports, the system will process the submission and immediately provide a unique reference ID number (format: INT-XXXXXXX) on the screen. This unique reference ID number will also be emailed to the reporter.

Your obligations are not met by entering the Reportable Events in business reports, such as call notes, emails to your manager, or internal social media sites.

Covered Persons should try to obtain as much of the following information to the extent feasible and provide to Amgen to assist Amgen in its follow up with patient(s):

- Patient identifier (date of birth or initials)
- A description of the Reportable Event
- Amgen Product Implicated (if applicable the lot number on product pack)
- Reporter Contact Details

U.S. Commercial field staff do not need to provide information related to an off-label use unless associated with an Adverse Event. However, U.S. Commercial field staff must report all other AEs, PCs, OSFs irrespective of whether the event is from on-label or off-label use.

Please note that any information collected about an individual person or persons must comply with applicable privacy and data protection laws and regulations, along with Amgen policies. If you have any questions or require direction, contact your local Amgen data protection officer or the Amgen Privacy Office.

Information about Reportable Events must be kept confidential. Covered Persons should not discuss any information concerning a Reportable Event with anyone except the reporting person or entity, supervising staff, staff in Global Patient Safety, Medical Information, Amgen Operations, and the Law Department, unless otherwise directed.

3. Covered Persons Responsibility for Compliance

Every Covered Person is required to follow and employ reasonable steps in preventing violations of (1) the Amgen Code of Conduct, (2) laws and regulations applicable in the relevant jurisdictions, and (3) Amgen policies and other governance documents applicable to him or her. Covered Persons are also required to report any conduct that may violate such laws, regulations, the Amgen Code of Conduct, and Amgen policies and other 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. 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) applicable laws and regulations, (2) know the Amgen Code of Conduct and other governance documents applicable to the activities they manage or supervise, (3) ensure their direct reports have appropriate training on compliance requirements to perform their job functions, and (4) supervise their direct reports with respect to compliance requirements and activities.

If Amgen determines that any Covered Person has violated this Policy, related standards, procedures or controls, applicable laws or regulations, or any governance documents, appropriate disciplinary measures will be taken, up to and including immediate termination of employment, to the extent permitted by applicable laws. The following is a non-exhaustive list of possible disciplinary measures to which Covered Persons may be subject (subject to applicable law): oral or written warning, suspension, removal of job duties/responsibilities, demotion, reduction in compensation, and/or termination of employment.

Subject to applicable 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 wrongdoing to governmental authorities. Nothing in this Policy changes the at-will nature of employment at Amgen, its affiliates or subsidiaries, where applicable. Amgen may also terminate the services or work engagement of non-employee Covered Persons for violation of this Policy.