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.

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 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 requiring reporting of Reportable Events to Amgen and that vendors are trained on these reporting requirements. Managers of Covered Persons must supervise their direct reports with respect to compliance requirements and activities within this Policy.

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-023004, Vendor Engagement of Safety Reporting Requirements for Commercial Programs*; and *MAN-002981, Management of Patient Support 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**.** Additionally, Covered Persons must ensure that the contracts with third-party vendors contain language consistent with the requirements of relevant global standard operating procedures requiring the collection of Reportable Events.

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 ▪ 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 ▪ 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

Term	Definition
	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. Examples include: ▪ Device that is damaged or broken ▪ Bent or blunt needles ▪ Missing or illegible labeling ▪ Inability of customer to administer the product ▪ Product with an unexpected color, appearance, or particles ▪ User error (i.e., an act or omission of an act that results in a different combination product or medical device response than intended by the manufacturer or expected by the user, where the user attempted to use the combination product or medical device in good faith and experienced difficulty or deficiency administering the product). Reports of misuse of a combination product or medical device (i.e., the intentional and improper use of a combination product or medical device not in accordance with the authorized product information) are not considered Product Complaints.

How to Report

Report information on AEs, OSFs and PCs by contacting any of the following:

- Amgen Safety Reporting Portal (ASRP): https://www.amgenintakeportal.com/

- 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: 8-447-3505 or +1-800-772-6436 (+1-800-77-Amgen)

Your reporting obligations are met by directly submitting Reportable Events via ASRP or by calling the appropriate office **within one business day**. 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 (except the U.S. Commercial field staff when off-label use is not associated with Adverse Events) should try to obtain details that will assist Amgen in its follow-up (e.g., a patient identifier, date of birth or initials, a description of the Reportable Event, the Amgen product implicated, and reporter contact details). If available, obtain the lot number on the product pack used. 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.