

## 1. Scope

Applicable to all Amgen staff members, consultants, contract workers, and temporary staff at all Amgen locations 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

The preparation, use, and dissemination of timely, accurate, and balanced promotional information about Amgen’s products and areas of therapeutic interest to Amgen, are essential to Amgen’s mission to serve patients. Promotion of biotech and pharmaceutical products approved by regulatory bodies (“Products”) is regulated in every country in which Amgen operates. Promotion regulations are designed to safeguard public health by ensuring that healthcare professionals and consumers are provided with information regarding the Product’s uses, risks, and benefits that is truthful, adequate, balanced, and based on valid scientific evidence and sound clinical medicine. Consequently, no public communication may be made with the intent of promoting Products as safe and effective for any use before regulatory approval of the Product for such uses is obtained.

It is Amgen’s policy that all promotional activities comply with all applicable laws and regulations. This Policy sets forth requirements designed to ensure Covered Persons comply with laws in the U.S. and other countries governing the preparation, use, and distribution of promotional information. Outside the U.S., Covered Persons who engage in promotional activities must comply with applicable codes of practice, as required by local trade associations in which Amgen is a member.

### Definition of Promotional Information

For the purpose of this Policy, “promotional information” refers to any information or material prepared, used, or disseminated by Covered Persons (or agents of Amgen), involving an express or implied claim about the use, effectiveness, or safety of an Amgen Product, that is intended to promote the prescription or use of such Product.

### Promotional Activities

When Covered Persons promote Amgen Products, all promotional discussions and promotional information prepared, used, or distributed by Covered Persons must be complete, accurate and not misleading. The following practices should be observed. Covered Persons must review the additional Amgen governance documents that address promotional activities and approval of promotional materials.

- On-label: Claims relating to the use, effectiveness, or safety of Amgen’s Products must be consistent with country-specific approved labeling and prescribing information.
  - Off-label promotion is strictly prohibited, and no communication may be made with the intent of promoting Amgen Products as safe or effective for any use before FDA or other regulatory approval for such use is obtained.
  - The word “safe” must never be used to describe a medicinal Product without proper qualification.
- Fair balance: When discussing Products, Covered Persons must always ensure their presentations provide “fair balance.” All safety information should be described fully and accurately; it should not be characterized as a positive Product attribute, or minimized in any way.

Full prescribing information must be provided in connection with every promotion or discussion concerning Amgen Products.

- Promotional materials: Only material that is approved by Amgen for promotional use may be used in connection with discussions about Amgen Products. Covered Persons are prohibited from creating or distributing “home-made” materials and from altering Amgen-approved promotional materials in any way.
- Statements concerning competitors’ Products: Covered Persons may make direct comparisons between an Amgen Product and a competitor’s Product regarding Product efficacy, safety or other characteristic only if such a claim is approved by Amgen and supported by substantial evidence (e.g., head-to-head clinical trials).
- Direct-to-consumer communications are subject to additional restrictions and must comply with applicable local laws and regulations.

#### **Product Reimbursement Information**

In the U.S., Covered Persons must keep the following in mind when providing information about Product reimbursement.

- Reimbursement information provided to patients, healthcare providers, payors and others must be accurate and not misleading.
- Reimbursement information or support provided to healthcare providers must not involve the unlawful promotion of unapproved uses of Amgen’s Products.
- All reimbursement assistance program materials provided to patients, physicians or others must be reviewed and approved by Amgen.
- Covered Persons may never discuss with healthcare professionals how much money a healthcare professional can make on the difference between the healthcare professional’s acquisition cost and reimbursement from Medicare or other third party payors (e.g., “spread,” “profit,” “return to practice” or other similar concept).

### **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.