

1. Scope

Applicable to all Amgen Inc. and subsidiary or affiliated company 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

It is Amgen’s policy to comply wherever it operates with all applicable laws, regulations, and codes of practice as required by local industry associations of which Amgen is a member. This Policy sets forth the following:

- Requirements for Interactions with Healthcare Providers (HCPs);
- Requirements designed to ensure Covered Persons comply with laws governing Promotional Activities, including the preparation, use and distribution of Promotional Information; and
- Principles regarding Scientific Exchange

Definitions

Term	Definition
Healthcare Provider	Any person or entity in a position to purchase, prescribe, administer, recommend or arrange for the purchase, sale or formulary placement of an Amgen product, including, but not limited to, physicians and physician groups, nurses, office practice managers, dialysis center personnel, free standing or hospital based dialysis centers, wholesalers, hospitals, pharmacists, medical directors, practice management companies, pharmacy benefit managers and group purchasing organizations, as well as any individual employed by such entities who is in a position to recommend, influence, or arrange for the purchase, sale, prescription or formulary placement of Amgen products.
Promotional Information	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.

Term	Definition
Research	Any activity intended to test the safety or effectiveness of Amgen’s products or to contribute to Amgen’s understanding of a product, product candidate, disease, therapeutic area or treatment alternative. For purposes of this Policy, Research includes, but is not limited to, pre-clinical studies, Amgen initiated clinical studies (regardless of phase), investigator initiated clinical studies (regardless of phase), drug or medicine utilization evaluations, patient registries, observational studies, analysis of existing data or drug development alliances. This definition does not include market research.
Scientific Exchange	The bona fide exchange of medical and scientific information or data by Covered Persons (1) through scientific dialogue that is conducted in a non-promotional context (e.g., including, but not limited to, publications, medical education, disease state discussions, dialogue related to Amgen- sponsored clinical trials or investigator-sponsored studies), or (2) in response to an unsolicited question or request for information from an HCP. Scientific Exchange specifically excludes the communication of Promotional Information.

Interactions with HCPs

The pharmaceutical and biotech industry’s interactions with HCPs are subject to regulatory oversight around the globe. The laws that address this area are sometimes referred to as anti-kickback or sponsorship laws. In all the countries in which Amgen operates, laws and regulations impose restrictions on economic benefits given by pharmaceutical and biotechnology manufacturers to HCPs. Penalties for violation of such laws and regulations can include imprisonment, criminal and civil fines and/or exclusion from government health care programs. As such, compliant and ethical interactions with HCPs are essential.

Covered Persons interact with HCPs in a wide variety of situations across Amgen. It is important to understand that this Policy and other Amgen documents governing interactions with HCPs apply in all settings, including activities undertaken by Covered Persons involved in sales and marketing, market research, product research and development, technical operations, and regulatory and governmental affairs.

When interacting with HCPs, Covered Persons must observe the following basic principles:

- Covered Persons must ensure that all interactions with HCPs are required by a legitimate need on the part of Amgen, as specified in relevant Amgen governance documents. These interactions include, but are not limited to, sales calls, arrangements with HCPs for consulting projects, speaking engagements and Research activities. In no event shall Research activities be used as a way of promoting Amgen products.
- Covered Persons must not promise or provide anything of value for the purpose of encouraging or inducing any HCP to purchase, prescribe, use or recommend Amgen products, to influence formulary status, where applicable, or to reward any such prior action.

- Where permissible under applicable law, Amgen may elect to permit Covered Persons to provide items of de minimis value and/or samples, in Amgen's sole discretion. Covered Persons are required to comply with Amgen governance documents relating to such activities.
- Covered Persons must adhere to all functional area processes relating to any HCP interaction.
- Any and all compensation to HCPs for activities performed or services rendered on behalf of Amgen must be the result of arm's length negotiations between the appropriate Covered Persons and the HCP. All compensation or other remuneration for any activities performed, or any other services rendered by HCPs must be commensurate with the services provided and reflect fair market value for the activities performed or services rendered. All such arrangements must be documented in writing.
- All written contracts with HCPs must contain a detailed description of the types of services to be provided, the standards to which such services are to be performed and the deliverables expected. Arrangements must be compliant in the jurisdiction of the HCP. For events, all applicable laws, regulations, and codes of practice in the jurisdiction where the event is held must also be followed.

In addition to the above, Research activities with HCPs are subject to the following:

- All Research must contribute to Amgen's understanding of a product, product candidate, disease, therapeutic area, or treatment alternative
- All Research covered under this Policy must be reviewed and approved by an appropriate review body within Research & Development ("R&D").
- Amgen R&D personnel are responsible for the selection of investigators and institutions for Amgen Research. Amgen Sales & Marketing personnel may recommend investigators and institutions for Research, but must not participate in the ultimate selection of investigators and institutions.
- All agreements for Research must be evidenced by a written contract that has been generated and approved by the Law Department.

Promotional Activities

The preparation, use and dissemination of timely, accurate and balanced Promotional Information about Amgen's products and information about areas of therapeutic interest to Amgen are essential to Amgen's mission to serve patients. Promotion of biotechnology and pharmaceutical products approved by regulatory bodies is heavily regulated. Promotion regulations are designed to safeguard public health by ensuring that HCPs 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.

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.

- 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

- No communication may be made with the intent of promoting Amgen products as safe or effective for any use before 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, and it must not be minimized in any way. Prescribing information must be provided in connection with promotion of Amgen products.
- Promotional materials: Only material that is approved by Amgen for promotional use may be used in connection with promotional 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.
- Where permitted, direct-to-consumer communications are subject to additional restrictions and must comply with applicable local laws and regulations.

Covered Persons must keep the following in mind when providing information about product reimbursement:

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

Scientific Exchange

The preparation, use and dissemination of timely, accurate and balanced scientific information about Amgen products and areas of therapeutic interest to Amgen are consistent with Amgen’s mission to serve patients. Communications by pharmaceutical and biotechnology manufacturers regarding the risks, benefits, safety and efficacy of products is subject to regulation in every country in which Amgen operates. Generally, regulatory agencies distinguish between promotional communications and the non-promotional exchange of scientific information.

Amgen is committed to Scientific Exchange that is:

- Not promotional in its nature and intent, and
- Truthful and non-misleading.

3. Additional Information

Covered Persons Responsibility for Compliance

Every Covered Person worldwide is required to follow (1) the Amgen Code of Conduct, (2) laws and regulations applicable in the relevant jurisdictions, 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) provide that 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 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 the 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.