Amgen GLOBAL CORPORATE COMPLIANCE POLICY

COMMUNICATIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

1.0 SCOPE

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

2.0 PURPOSE

As a member of the pharmaceutical and biotech industry, Amgen's communications with members of the Healthcare Community (HCC) are subject to regulatory oversight in every country in which it conducts business. Those countries have laws and regulations relevant to Amgen's drug development, manufacturing, marketing, and other commercial activities. For example:

- Most countries have specific laws and regulations for the pharmaceutical industry and have given regulatory oversight responsibility to one or more governmental agencies.
- The healthcare systems in many countries are operated by the government and healthcare providers (e.g., physicians and hospital personnel) who are frequently government employees. You must be particularly sensitive to this issue because a country's government is often both the regulator of our products as well as a customer.
- Health policy makers may seek (or you may proactively provide) your advice regarding health system design and functioning, laws or regulations, or other policies affecting the regulatory, reimbursement, or business environment for Amgen and/or the biopharmaceutical industry, consistent with appropriate local or functional approval processes.
- Practices generally accepted in one country might not be lawful or appropriate in interactions with government agencies or personnel in other countries.
- Promotion of biotechnology and pharmaceutical products approved by regulatory bodies is heavily regulated. Promotion regulations are designed to safeguard public health by ensuring members of the HCC 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 data.

3.0 POLICY

It is Amgen's policy to comply with all laws and regulations that govern the promotion and provision of scientific information.

Penalties for violation of such laws and regulations can include imprisonment, criminal and civil fines, and/or exclusion from government healthcare programs. As such, compliant and ethical interactions with the HCC are essential.

Definitions

Term	Definition
Government Official	Government Official means any person acting in an official capacity on behalf of a government, agency, department or instrumentality of another country, including, in some countries, government-owned businesses such as hospitals. It also includes any political party or candidate for political office and their representatives.
Healthcare Community (HCC)	Healthcare Professionals, Healthcare Institutions or Healthcare Organizations, Members of the Scientific Community, Payors, Purchasers, Professional Societies and Trade Associations, Patients, Patient Organizations, and patient advocacy groups. This definition includes members of the Healthcare Community who are officers or employees of the government, a government agency or department, or a government-owned or government-operated institution (such as a hospital, university, or research center) and any other Government Officials.
Healthcare Institution (HCI) or Healthcare Organization (HCO)	A facility that provides health maintenance or treats illness and injury and can include any hospital, convalescent hospital, dialysis center, health clinic, nursing home, extended care facility, or other institution devoted to the care of sick, infirm, or aged persons and in a position to purchase or influence a purchasing decision for any Amgen product or service.
Healthcare Professional (HCP)	Any person 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, 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.
Member of the Scientific Community	Any scientist, researcher, professor of science and/or medicine, educator, student, research collaborator, intern, laboratory technician, and university or college as well as any individual employed by such entities.
Patient	An individual awaiting or under medical care or treatment in an area of interest for Amgen.

Term	Definition
Patient Organization	Not-for-profit organizations (including the umbrella organizations to which they belong) mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers.
Payor	Entities that are responsible for the financing or reimbursement of costs associated with health care services (e.g., Pharmacy Benefit Managers (PBMs), third party payors, health plan sponsors).
Professional Association or Society/Trade Association	A non-profit or tax-exempt organization seeking to further a particular profession within the healthcare industry, the interests of individuals engaged in that profession, and the public interest.
Purchaser	Individuals or entities, including wholesalers, pharmacies, and group purchasing organizations, that purchase Amgen product to sell to members of the Healthcare Community or that are authorized to act as a purchasing agent for a group of individuals or entities who furnish healthcare services.

3.1 Promotional Activities

The preparation, use, and dissemination of truthful and non-misleading Promotional Information about Amgen's products and information about areas of therapeutic interest to Amgen are essential to Amgen's mission to serve patients. Promotional Information is any information or material prepared, used, or disseminated by Amgen staff that is consistent with the approved product label, 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. When you promote Amgen products, all promotional discussions and Promotional Information prepared, used, or distributed by you must be complete, accurate, and not misleading.

The following practices govern promotional activities and the approval of promotional materials:

- No communication may be made with the intent of implying Amgen products as safe or effective for any use before regulatory approval for such use is obtained. The word "safe" must not be used to describe a medicinal product.
- Claims relating to the use, effectiveness, or safety of Amgen's products must be consistent with country-specific approved labeling.
- Off-label promotion is strictly prohibited.
- When discussing products, you must always ensure their presentations provide "fair balance." Safety information should be described fully and accurately, and it must not be minimized in any way. Prescribing information must be offered in connection with promotion of Amgen products.

- Only material that is approved by Amgen for promotional use may be used in connection with promotional discussions about Amgen products. You are prohibited from creating or distributing "home-made" materials and from altering Amgen-approved promotional materials in any way.
- You 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.
- Direct-to-consumer communications (including promotion) is only allowed if permitted by local law. Where permitted, direct-to-consumer communications are subject to additional restrictions and must comply with applicable local laws and regulations.

Communications with payors and/or health technology assessors must be truthful and non-misleading. Depending on the jurisdiction, certain interactions may not be deemed promotional.

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

- Reimbursement information provided to members of the HCC and others must be accurate and not misleading.
- Reimbursement information or support provided to members of the HCC must not involve the unlawful promotion of unapproved uses of Amgen's products.
- All reimbursement assistance program materials provided to members of the HCC or others must be reviewed and approved by Amgen.
- You must never discuss the personal economic benefit to members of the HCC from government or other third-party payors (e.g., "spread," "profit," "return to practice," or other similar concepts).
- Where applicable, you must not disclose reimbursement information that is subject to confidentiality (e.g., part of confidential pricing and reimbursement contracts or agreements).

3.2 Scientific Research and Exchange

Amgen may sponsor, fund, or otherwise support Scientific Research activities that fill legitimate research needs on the part of Amgen. Scientific Research is any activity intended to test the safety or effectivenss of Amgen's products or product candidates, or to contribute to Amgen's understanding of a product, product candidate, disease, therapeutic area, or treatment alternative. All Scientific Research must be conducted or overseen by the Research and Development (R&D) organization. R&D personnel are responsible for all steps of the design, conduct, and/or publication of Scientific Research. Commercial personnel cannot participate in: the approval of the publication of Scientific Research, the Investigator Sponsored Studies (ISS) decision process, or the selection of investigators or sites for Amgen sponsored research activities. All agreements for Scientific Research must be evidenced by a written contract that has been generated and approved by the Law Department.

Communications with members of the HCC about Scientific Research must be made only in furtherance of the goals of Scientific Research. 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, the bona fide exchange of medical and scientific information or data (1) through scientific dialogue that is conducted in non-promotional contexts or (2) in response to an unsolicited question or request for information on unapproved uses of an Amgen product that is:

- not promotional in its nature and intent, and
- truthful and non-misleading.

- Follow applicable processes for the review of the Scientific Exchange material being developed.

3.3 Policy Research and Exchange

Amgen may sponsor, fund, or otherwise support policy research and communication activities that fill legitimate research needs of health systems, regulatory authorities, governments, or Amgen and/or the biopharmaceutical industry. Policy research can be conducted by local, regional, and global Amgen entities or vendors for legitimate business purposes, with oversight provided by the appropriate policy organizations at Amgen.

Communications with members of the HCC about policy matters or research must be made only in furtherance of legitimate business purposes and must be non-promotional, truthful, and non-misleading. Only materials which have been approved for external use may be used.

3.4 Joint Interactions

3.4.1 Joint Interactions with the HCC by Commercial and R&D Staff

Commercial and R&D staff may jointly visit members of the HCC provided that such a meeting is appropriate in accordance with other applicable regional or local standards and procedures, and all materials used during the meeting have appropriate approval to be used in such a meeting. Commercial staff should limit their discussions to promotional information and materials.

3.4.2 Joint Interactions between Commercial and R&D Staff

The Commercial and R&D organizations are separate functions and should pursue their own function's goals and objectives (i.e., each function must have separate objectives and tactics). It is permissible to provide information to the other organization that may inform their decisions and impact the ability to meet their goals. It is not appropriate to mandate or direct the goals and objectives of the other function nor to make decisions that belong to the other organization.