Distributor
Compliance Manual

Contents

1 General Principles

1.1. Introduction

This document supplements the standards outlined in the Master Distribution Agreement (MDA) by setting forth the compliance principles Amgen's distributors must follow. Under the distributor's contractual obligations to Amgen, distributors will comply fully with all applicable laws, regulations, and industry codes (e.g., IFPMA, EFPIA, local codes, etc.; if no local Code, follow the principles of the IFPMA Code) including, but not limited to, anti-bribery, anti-corruption, export control, trade sanction, privacy, and sales and marketing of pharmaceutical and medical device products. Failure to comply with any applicable law and/or regulation could result in termination of the MDA between Amgen and the distributor (in accordance with the terms of the MDA).

Questions regarding any of the compliance principles set forth in this document should be raised promptly to the appropriate Amgen representative for clarification.

1.2. Policies and Procedures

Each Amgen distributor is contractually obliged to comply with applicable laws, rules or regulations concerning or relating to public or commercial bribery or corruption as well as the Amgen Code of Conduct as specified in the MDA. The Amgen Code of Conduct sets forth the key legal and ethical principles that all Amgen employees and third parties (including distributors engaged by Amgen) must follow.

Additionally, distributors are expected to adhere to principles and guidance provided during training(s) around bribery and corruption and healthcare compliance.

Amgen's Ethics policies and Code of Conduct are publicly available on Amgen's corporate website, www.amgen.com. Copies of the above stated materials are available upon request.

1.3. Responsibility for Compliance

Each Amgen distributor is responsible for ensuring that it complies with the expectations set forth in this document, the obligations created by the distributor's contract(s) with Amgen (including Amgen policies incorporated into the contract(s), and all applicable laws and regulations. Amgen expects that its distributors will implement controls to prevent non-compliant activities, including activities that may otherwise be common local custom. Identifying an activity as "common business practice" is not an acceptable justification for activities that may not be legal or compliant with principles set forth here.

Each distributor will have a designated employee who shall oversee compliance requirements to ensure compliance with applicable laws and regulations as well as with setting forth applicable standards. The distributor will ensure that Amgen is kept updated with the name(s) and contact information of these employee(s).

In addition to the specific roles and responsibilities set out in the MDA regarding pharmacovigilance, product surveillance, regulatory affairs, and quality, Amgen expects each distributor to implement proportionate and adequate controls to ensure that any activities that the distributor conducts in relation to Amgen products are compliant. These controls should include procedures for:

- Pre-approval by Amgen of promotional materials (such as detail aids, advertisements, and leave- behind items/pieces (printed or in electronic format)) used with HCPs and non-promotional materials (such as disease state education, patient materials, Medical Science Liaison (MSL) materials (printed or in electronic format)) used with HCPs, other members of the healthcare community and general public.

- The provision of samples, evaluation products, and other free-of-charge goods (including for compassionate use), as well as the provision of discounts and/or rebates where allowed by local laws and consistent with the IFPMA Code as well as local codes of practice.

- Activities involving members of the healthcare community such as those relating to sponsorship, events, consultancy arrangements, hospitality, and entertainment (prohibited), as well as all other promotional activities, scientific exchange and patients' programs. Process for review and validation by Amgen of high-level business plans with such activities must be established

- Capturing consent & data for transparency disclosure requirements (if applicable).

    - These controls should include expenditure limits, requirements for supporting documentation collection and review and should provide guidance regarding acceptable venues for interactions and appropriate interactions with HCPs, other members of the healthcare community, patients, patients organizations representatives and care givers.

    - These controls should be consistent with the IFPMA Code as well local codes of practice for the marketing of pharmaceuticals and medical devices, and applicable local laws and regulations.

- Maintenance of complete and accurate accounting records.

    - These controls should address the records necessary to support expense reimbursement requests and other expenditures.

For avoidance of any doubts, any pre-approval of any business plan with and/or activity by Amgen (as described above) does not relieve the distributor from any

liability towards any third parties or regulators. All distributors remain solely responsible for their activities and are required to follow applicable laws and standards as defined above. Distributor shall ensure that any activity submitted for Amgen's approval has been already reviewed and approved by respective compliance and legal function of the distributor.

Amgen distributors will inform Amgen of material changes to ownership (including executive positions) as well as material changes, if any, to distributor's compliance practices with respect to this document.

1.4. Good Distribution and Manufacturing Practices

Distributors will comply with applicable laws and regulations relating to the manufacturing and distribution of pharmaceuticals and medical devices. Regulatory authorities assess compliance with these requirements through inspections and other activities.

Amgen reserves the right to audit its distributor's compliance with these requirements and the specific contractual obligations relating to these practices, as set out in the technical agreement (e.g., quality agreement and supply terms) between the distributor and Amgen.

1.5. Licenses and Permits

Pursuant to the terms of the MDA, each Amgen distributor must be in possession of a wholesale dealer's license or equivalent and be approved and/or authorized to distribute pharmaceuticals and / or medical devices by the local ministry of health or respective governmental health body. A copy of this license and an English translation must be made available to Amgen. Where the distributor is acting as the Marketing Authorization Holder for an Amgen product or products, the activities delegated to Amgen and the responsibilities of the distributor must be clearly agreed upon to ensure compliance with the Marketing Authorization requirements.

1.6. Training

Distributors must cooperate with Amgen's compliance training requests by, for example, ensuring that the relevant officers, employees, and contractors of the distributor participate in the training. In addition to the training scheduled by Amgen, Amgen expects that each distributor will provide appropriate training on a regular basis to its officers, employees, and contractors (if applicable) on compliance issues and the policies and procedures that are applicable to their functions.

1.7. Certification

Amgen requires its distributors to certify every 2 (two) years that they are in compliance with applicable laws and regulations, as well as the policies listed in the MDA. Amgen will provide the requisite forms for documenting this certification. Failure to comply with requests for certification could result in termination of the agreement between Amgen and the distributor in accordance with the terms of the parties' contract.

1.8. Reporting Suspected Violations

Distributors must report to Amgen any known or suspected violations of the applicable laws, regulations, and Amgen policies in relation to the business activities that the distributor carries out in connection with Amgen products. Such reports may

be made to the distributor's business contact at Amgen or to Amgen's Business Conduct Hotline, which is accessible through Amgen's corporate website, www.amgen.com.

1.9. Reimbursement of Pre-Approved Expenses

Where MDA allows to be reimbursed by Amgen for payments, distributors must accurately allocate the payment to the appropriate Amgen product or group of products and type of activity. Amgen expects its distributors submit invoices with adequate supporting documentation (e.g., written and properly executed contracts, itemized invoices, fee schedules and time sheets, etc.) to ensure amounts spend are for legitimate goods and/or services in relation to Amgen products and provided in accordance with fair market value and based on a legitimate business need. To be reimbursed by Amgen for payments made to HCPs (including costs for travel, hospitality, meals, sponsorships, and consulting activities) the distributor must clearly identify the individual HCP to enable all such payments to be tracked and reported for regulatory purposes, as needed.

Permissible activities (as defined below in Section 5) that are directly reimbursed by Amgen, require Amgen's pre-approval.

Amgen will refuse payment and/or reimbursement for any activity that does not comply with applicable laws, regulations, or Amgen policies incorporated by Amgen's agreement with the distributor.

1.10. Good Pharmacovigilance and Product Surveillance Practices

Distributors must comply with applicable pharmacovigilance and product surveillance laws and regulations in connection with distribution of Amgen's pharmaceuticals and medical devices. Specific requirements are set out in the Pharmacovigilance Agreement between distributor and Amgen. Compliance with these requirements will be regularly monitored by Amgen and during inspections by regulatory authorities. Amgen also reserves the right to audit the distributor's compliance with these requirements.

1.11. Appointment of Agents, Sub-Distributions, or other Sales Channel Intermediaries

Under the terms of Amgen's agreements with its distributors, distributors may not appoint sub-distributors, or agents to distribute Amgen products. Nor may an Amgen distributor subdivide, transfer, or assign any of its rights or obligations under its agreement with Amgen. If a distributor wishes to use a sub-distributor or other sales channel intermediary in connection with the sale and promotion of Amgen products, it must first seek written approval from Amgen.

Distributors are authorized to sell Amgen's products to other entities authorized to purchase pharmaceutical products (wholesalers, pharmacies, hospitals, etc.) without Amgen prior approval.

1.12. Political Contributions

Amgen strictly prohibits its distributors from making political contributions related to Amgen or Amgen products. Political contributions include (but are not limited to) monetary payments to political campaigns, political parties, and candidates.

2 Anti-Bribery and Anti-Corruption Requirements

2.1. Prohibition of Bribery

Distributors must conduct all activities in accordance with applicable anti-bribery and anti-corruption laws. Information regarding Amgen's Anti- Bribery and Anti-Corruption principles is available in our Global Anti-Bribery and Anti-Corruption Policy accessible via www.amgen.com. Distributors must notify Amgen immediately if subject of an investigation.

Distributors will adhere to the following general standards:

- Promising, giving and/or receiving a bribe in any form is prohibited (this includes in kind transfers or business favors)
- Distributors must not make payments, offers or promises of payment (of money or any other item of value) with the intent to inappropriately influence the recipient. This prohibition extends to interactions with government officials and employees, as well as private individuals and private sector officers and employees.
- Distributors must not make any facilitation (so-called "grease" or expediting) payments in connection with Amgen or Amgen products even where permitted by local law, rule, regulation, or guideline.
- Distributors must maintain complete and accurate records of all financial transactions relating to Amgen or Amgen's products. Records of all such transactions must be provided to Amgen upon request.
- Cash payments are not permissible to support Amgen related activities. Use of cash must be pre-approved by Amgen only in exceptional circumstances.

2.2. Business Interactions with Government Officials and Employees

Distributors will comply with the FCPA, U.K. Bribery Act, and other international anti-corruption and anti-bribery laws. Those laws, and related regulations and industry guidelines prohibit offering, promising, or providing gifts, benefits, or anything of value to government officials, employees, or other individuals while knowing that they will be provided to a government official or employee to induce, obtain, or retain business (including sales of pharmaceuticals or medical devices) or for an improper business advantage. In limited circumstances, the provision of compensation to HCPs who are government officials or employees is permissible if provided in strict compliance with all applicable laws, regulations, and industry guidelines, as well as the expectations set forth in section 5.6 Consultancy Services with Healthcare Professionals).

3 Fair Competition Requirements

3.1. Anti-Competitive Behaviour

Competition laws are designed to protect consumers and competitors against unfair business practices and to promote and preserve fair competition. Violations of these laws can result in heavy sanctions for both Amgen and its distributors.

Distributors must know, understand, and comply with all applicable antitrust and competition laws and regulations that apply to their activities. Although laws vary from country to country, it is generally unlawful to collude with competitors to fix prices or in any way allocate market share and/or to abuse a dominant market position. Many of Amgen's products enjoy a dominant position in many markets and therefore are subject to additional constraints in terms of acceptable commercial practices.

Distributors will adhere to the following general standards:

- Distributors should agree upon commercial terms only where they are legally permissible, in keeping with the usual practice in the pharmaceutical or medical device industry, and capable of passing cost savings or benefits on to the customer or consumer.
- All commercial terms must be transparent, must be agreed in advance, and must appear on the invoice and written and properly executed contract.
- Under no circumstances may pricing or commercial policies be shared, discussed, or agreed with competitors.
- Under no circumstances may any territory be divided up with a competitor or allocated exclusively to a competitor.
- Competitors must be treated fairly and with respect, and nothing must be done to prevent them from competing fairly for customers.
- Distributors may recommend the downstream sale prices for customers, wholesalers, and distributors, but they may never be set or fixed.
- The supply of one product to a customer may never be made conditional upon that customer's use of another product.
- The supply of product to a customer should never be made conditional upon that customer not using a competing product.
- Under no circumstances should a customer ever be treated differently or given adverse commercial terms for using a competing product.

4 Privacy and Data Protection Requirements

4.1. Privacy and Data Protection Laws

Distributors must conduct all activities in accordance with applicable privacy and data protection laws. Privacy and data protections laws are designed to help individuals control the use of their personal information. Violations of these laws can result in sanctions for both Amgen and its distributors.

Distributors must know, understand, and comply with all relevant privacy and data protection laws that apply to their activities.

Further, Amgen expects that its distributors will adhere to the following general standards:

- Appropriate contractual provisions are required when collecting, using, or processing information that identifies individuals.
- Appropriate controls (including notice and consent mechanisms) may be required when collecting, using, or processing personal information.
- Distributors may only transfer or provide access to personal information to a third party that will protect and process that information in a manner consistent with activities disclosed in the related privacy notice.
- Distributors must obtain consent and document such consent where required by local law, before processing personal information.
- Distributors must adhere to Amgen's policy and procedures regarding reporting privacy incidents and cooperate with any resulting investigation. Information regarding Amgen's privacy principles is in Amgen Global Protection and Personal Information Policy accessible via www.amgen.com.
- Distributors must implement appropriate security measures to protect personal information.

5 Healthcare Compliance Requirements

Healthcare compliance requirements are mandatory for compliance with by all Amgen distributors. The MDA reflects the scope of distributor's permissible activities. This section does not, and should not be understood to, expand the scope of any Amgen distributor's permissible activities. Rather, the information set forth in the following section applies to the range of activities that Amgen may specifically authorize certain distributors to engage in. To the extent a distributor's MDA authorizes them to engage in the activities described below, Amgen expects that the distributor will understand and adhere to these standards. Permissible activities that are directly reimbursed by Amgen, require Amgen's pre-approval.

Distributors' relationships with HCPs and other stakeholders are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing HCPs about medicines, providing scientific and educational information and supporting medical research and education. In order to successfully deliver upon that Distributors shall ensure that the below listed principles are followed.

5.1. Direct-to-Consumer Advertising

Direct-to-consumer advertising of pharmaceuticals and medical devices is generally not permitted, and subject to certain restrictions and conditions on a country- by-country basis. Advertising to HCPs is not regarded as direct- to- consumer advertising but must be done in accordance with the requirements set forth in section 5.2 below. If DTC is permitted, it is subject to additional guidance from Amgen. Distributors may provide the general public with information that does not constitute advertising subject to applicable local laws and regulations as well as accepted market practice.

5.2. Promotional Materials and Activities

Distributors' promotion of Amgen products must comply with applicable laws and regulations regarding pharmaceutical and medical device advertising in accordance with the product's approved label. At a minimum, any promotional materials must be accurate, balanced, fair, objective, substantiated, and neither misleading nor disparaging. As the MDA provides, all promotional materials are required to undergo pre-approval by Amgen.

The use of «hotlines» for advertising pharmaceutical products is not permitted.

Provision of branded promotional items i.e., gimmicks, is not permitted.

5.3. Provision of Medical Samples

Distributors must abide by local laws, regulations, and industry guidelines governing the provision of medical samples of pharmaceuticals and medical devices, which vary greatly from country to country. Samples may be provided to an HCP in response to his/her signed and dated written request (and/or in accordance with relevant SOP) to enable that HCP to familiarize himself/herself with the product once authorized in the country in which it is to be distributed. Samples must be limited in number and distributors must maintain an adequate system of control and accountability for samples and sample programs.

In addition, the provision of samples as a bribe or as an inducement to recommend, prescribe, administer, purchase, sell, and/or use a product is inappropriate and, in some countries, illegal.

5.4. Sponsorships, Events, Meetings, Hospitality and Gifts

Laws, regulations, and industry guidelines prohibit offering, promising, or providing anything of value (including sponsorships, hospitality, gifts, and payments associated with events, meetings, and congresses) directly or indirectly to HCPs as an inducement to recommend, prescribe, administer, purchase, sell, and/or use a pharmaceutical or medical device. These prohibitions apply to Amgen distributors' scientific and medical support for Amgen products, as well as to their sales and promotional activities.

The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an "Event") for HCPs organized or sponsored by a company should be to provide scientific or educational information and/or inform HCPs about products.

Distributors will not provide gifts to HCPs.

5.5. Items of Medical Utility and Informational / Educational items

Items must not be provided with the intent of, directly or indirectly influencing or encouraging the recipient to purchase, prescribe, refer, sell, arrange for the purchase or sale or recommend formulary placement of any Amgen product, influence regulatory or reimbursement decisions, secure or retain business, secure an improper advantage or be used to reward past or future business.

Items can only be provided if the item is allowed under the local law and industry codes (e.g., IFPMA, EFPIA, etc.; if no local code, follow principles of the IFPMA Code), it must not provide personal benefit to the recipient or be provided to cover ordinary business expenses. Some countries require Items to be submitted / notified to local industry association or authorities.

5.6. Consultancy Services with Healthcare Professionals

Laws, regulations, and industry guidelines prohibit offering, promising, or providing anything of value (including compensation) to HCPs as an inducement to recommend, prescribe, administer, purchase, sell, and/or use a pharmaceutical or medical device. However, entities generally may retain HCPs to provide genuine professional services in exchange for a fee that reflects the fair market value of the service and is commensurate with the service provided.

Distributors will adhere to the following general standards when entering into consultancy services relationships with HCPs:

- There must be a clear business need for the engagement of the HCP and that need will dictate the duration and scope of the engagement.

- All engagements with HCPs must be approved in accordance with the distributor's processes and recorded in the form of an approved, fully executed written agreement prior to services provision or making associated arrangements. Agreements shall be dated.

- HCPs must be selected based on their qualifications, experience, and expertise, as well as their ability to provide a service of value (not on their status as a prescriber, purchaser, or user of Amgen products).

- All payments to HCPs under a consultancy agreement must be in accordance with the fair market value and for fees incurred for actual services rendered and accounted for accurately.

- Distributors should only pay for reasonable expenses incurred by HCPs in carrying out the services if the HCPs provide appropriate receipts for their expenses.

- If applicable laws or regulations requires pre-disclosure of consultancy engagements, the distributor must ensure that all consultancy engagements are declared to the relevant authorities in advance.

5.7. Pricing, Discounts, Rebates, and Tenders

Discounts, rebates, and other similar commercial arrangements are standard industry practice in many countries, and they can provide qualitative and quantitative benefits to customers and consumers. Amgen expects that its distributors will observe applicable laws, regulations, and industry guidelines that govern these types of commercial arrangements and ensure that any such arrangements are not regarded as anti-competitive behaviour (see section 3 on Fair Competition).

Distributor support (e.g. donations or product samples) must not be offered to members of the healthcare community to disguise discounts.

Schemes which enable purchasers or the employees of purchasers to personally benefit such as by receiving vouchers instead of a discount must not be offered or provided.

Amgen distributors must notify appropriate Amgen business contact prior to engaging in public tendering-related activities concerning Amgen products.

5.8. Donations and Grants

Amgen does not permit its distributors to provide donations or grants to individual HCPs or government officials. Amgen distributors may give donations and grants to institutions or charities, provided that they are approved in accordance with the distributor's processes.

Distributors will adhere to the following general standards:

- Grants or donations are restricted to the enhancement of patient care or genuine clinical research and not linked to the sale or promotion of Amgen products.

- Grants or donations must not be provided as a result of the recipient's (or associated HCP's) records of recommending, prescribing, administering, purchasing, selling, and/or using Amgen products and must be free from commercial influence.

- The provision of grants or donations must not be conditional upon a requirement that the recipient (or associated HCPs) recommend, prescribe, administer, purchase, sell, and/or use any Amgen product.

5.9. Patient Support and Affordability Programs

Provision of value under PSPs and PAPs cannot serve as an inducement to use, purchase, prescribe or recommend or refer Amgen products or be used as a reward for past or future business or impact a formulary decision on Amgen products.

Patient Support and Affordability programs shall not be used as a tool to drive sales, or a promotional tool in interactions of the sales representatives and members of the healthcare community. Where the local industry codes and regulations allow for that Sales Rep may notify HCPs of existing PSPs and PAPs, however, the amount of information they deliver shall be limited and must not be cited as an incentive to

prescribe and to also avoid any perception of the program being used as a sales or promotional tool.

PSP and PAPs must not affect the HCP's freedom to choose medication.

Advertising of a prescription drug to a patient is prohibited even if the drug has been prescribed to that patient.

Distributor shall not seek a return on investment from any product or financial / (indirect) non-financial support or services provided to patients. No sales KPIs or objectives set.

5.10. Product Training and Educational Support for Healthcare Professionals

Product training and education for HCPs is permissible in many countries, provided that any such activities comply with applicable laws and regulations, including those that prohibit inducements and off-label promotion.

Distributors will adhere to the following general standards:

- The provision of product training and education must not be conditioned on a requirement that the recipient recommend, prescribe, administer, purchase, sell, and/or use any Amgen product.

- Product training and education must occur at venues that are appropriate for the nature of the training or education (and that are not lavish or extravagant). In selecting a venue, the distributor may consider the convenience of the attendees.

- Product training and education conducted by distributors must only discuss on-label uses of Amgen products.

- Distributors may support HCPs in attending independent continuing medical education events subject to appropriate internal approval procedures.

- Product training materials for HCPs must be pre-approved by Amgen.

5.11. Product Training and Education for Sales Representatives

Distributors must train their sales representatives so that they are familiar with the relevant requirements of applicable laws, regulations, and industry guidelines relating to the sales and marketing of pharmaceuticals and medical devices. Amgen distributors' sales representatives must be adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the Amgen products that they promote. All sales representatives must also be trained to report adverse events and adhere to pharmacovigilance requirements.

5.12. Off-Label Promotion

Laws, regulations, and industry guidelines prohibit the promotion of pharmaceutical products and medical devices outside the approved product labelling (so-called "off-label" promotion). Distributors must only promote Amgen products in line with the products' approved labelling.

5.13. Scientific (Medical Information) Service

Distributors must implement a service to respond to requests for scientific information regarding Amgen's products from HCPs, including requests for "off-label" information. This service may be provided in-country or by a regional Amgen function.

5.14. Clear Distinction between Commercial and Medical Activities

Scientific events must not be used for promotional activities. For example, scientific advisory boards must not be held to recommend, promote, or market Amgen's licensed or unlicensed products. In addition, distributor sales incentivized staff is not allowed to attend such events.

5.15. Omni-channel and other Digital Initiatives

Data privacy, security and consumer protection laws vary greatly from country to country, and therefore distributors must ensure that they are compliant with applicable laws, regulations, and industry codes (e.g., IFPMA, EFPIA, etc.; if no local code, please follow the IFPMA Code principles) when planning to develop any omni-channel or digital initiatives (including websites, webinars, e-mail campaigns, disease awareness sites, and apps). All omni-channel and digital initiative content must be pre-approved by Amgen in accordance with section 5.2 (Promotional Materials and Activities).

6 Record Retention, Audit and Monitoring, and Remedial Actions

6.1. Record Retention

Amgen distributors must maintain business records in accordance with applicable laws and regulations, as well as the contractual obligations imposed by the agreement between Amgen and the distributor.

6.2. Auditing and Monitoring

Amgen has the authority to audit and monitor compliance under the terms of Amgen's contract with the distributor, including Amgen policies that are incorporated by the contract governing the distributor relationship. The nature, extent, and frequency of Amgen's monitoring reviews and audits of the distributor will vary according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations. Distributors are obligated by contractual provision to cooperate fully and in good faith with Amgen's monitoring and auditing activities.

6.3. Remedial Action

Amgen is committed to taking consistent and appropriate action to address inappropriate conduct and to deter future misconduct. Accordingly, Amgen responds promptly to actual or suspected violations of applicable laws, regulations, and Amgen policies and will take appropriate remedial action after considering the circumstances of each particular issue. Distributor is expected to cooperate with Amgen during investigations including but not limited to retaining/ providing additional documentation, making relevant distributor employees available upon request, and maintaining confidentiality during the course of review. Remedial action for a distributor's non-compliant activities may include a range of measures up to and including termination of the MDA (under the terms of the contract between Amgen and the distributor). Intentional, material, and/or concealed violations of applicable laws, regulations, or Amgen policies will be subject to severe sanctions. Nothing in this provision, however, shall be construed to waive, limit, or modify, any of Amgen's right or remedies under Applicable Law or the MDA, which shall remain in full force and effect.

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