Methodological Note 6.0

for EFPIA & Local Industry Association Disclosure Codes

INTRODUCTION

Amgen is committed to transparent interactions with Members of the Healthcare Community (MHCC) and Patient Organizations (PO). Our interactions take place through collaboration during early scientific research, clinical trials, medical and scientific education, all of which are intended to advance patient care by bringing innovative medicines to patients.

These individuals and organizations are the primary points of contact with patients; they offer expert knowledge on patients' behavior and management of diseases. This plays a major role in informing Amgen's efforts to improve patient care and treatment options – which is essential to improving patient outcomes.

Disclosing Transfers of Value (ToVs) such as payments and other support we make to MHCC and POs will enhance the public understanding of why interactions are necessary to improve patient care.

Amgen complies with disclosure requirements under applicable pharmaceutical industry codes and laws in each country where we operate, conducting business with strong ethical principles and the highest integrity.

This document summarizes the methodologies used by Amgen to prepare disclosures and identify ToVs.

This Note applies to the 36 European Federation of Pharmaceutical Industries and Associations (EFPIA) member countries[1], as well as Luxembourg, where Amgen has interactions with MHCC and POs.

1. DEFINITIONS

1.1. RECIPIENTS

Amgen compensates Members of the Healthcare Community (MHCC, e.g., HCPs, HCOs) and Patient Organizations (POs) for the valuable insights and time they offer. We also provide funding for medical education either directly to HCPs, via HCOs or via specialized third-party service providers (Professional Conference Organizers, PCOs). In line with legal or code requirements, Amgen will publicly disclose the ToVs it makes to MHCC and POs (hereafter 'Recipient').

Amgen utilizes both an internal and a proprietary commercial database to obtain the official name, principal business address, and where required, specialty and unique country identifier are taken for disclosure. If a

[1] Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Macedonia, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, and the United Kingdom

Recipient cannot be found in the proprietary commercial database, Amgen will capture the required information for disclosure in its internal database, based on the information provided during the contracting process.

Where Amgen provides ToVs for medical education to HCPs through an HCO or PO, the ToVs are disclosed against the HCO or PO. However, if Amgen selects the individual HCP who benefits from an educational event conducted by an HCO or PO, the ToVs will be disclosed individually under each HCP's name, provided consent has been obtained in accordance with applicable Data Privacy Laws.

Ethics Committees are designated to approve, monitor, and review biomedical and behavioral research involving humans. Amgen does not make payments to HCPs via an Ethics Committee. Payment or fees to Ethics Committees under HCOs is reported.

A Clinical Research Organization (CRO) is an organization that provides support to the pharmaceutical, biotechnology and medical device industries in the form of research services outsourced on a contract basis. CROs are not considered HCOs, however where Amgen makes ToVs to HCPs/HCOs through CROs, the indirect ToVs are disclosed in the relevant disclosure category.

Where a third party is a Professional Conference Organizer (PCO), Amgen discloses the ToVs in the appropriate category under the name of the sponsored MHCC or PO (as the ultimate beneficiary), or by event title and the name of the PCO. If the PCO independently organizes an event (i.e., there is no sponsored / identifiable MHCC or PO), Amgen discloses the sponsorship under the PCO's name, with reference to the name of the event.

1.2. TRANSFERS OF VALUE (ToV)

DONATIONS AND GRANTS

Amgen provides donations/grants to Recipients (not-for-profit HCOs and POs) to:

- support science, technology, medicine, healthcare, research, education, or the needs of patients / caregivers,
- educate the public / patients on disease states, medical conditions, science, or technology,
- further genuine philanthropic and charitable purposes that are consistent with Amgen's scientific and disease-state interests.

Such donations (either cash or benefits in kind) are formalized in agreements that describe the purpose of the donation and the related ToVs.

Donations and grants, and humanitarian aid in the form of Amgen medicinal products will be disclosed under "*Donations and Grants*" category in the HCP/HCO Disclosure reports.

CONTRIBUTION TO COST RELATED TO EVENTS AND SPONSORSHIP

We include ToVs Amgen provides to Recipients for educational support at medical / educational events or congresses: registration fees, travel, and accommodation (e.g., cost of flights, trains, car hire, tolls, parking fees, taxis, and hotel accommodation, etc.).

FEE FOR SERVICE AND CONSULTANCY

ToVs resulting from or related to contracts between Amgen and MHCC (HCPs or HCOs) under which MHCC provides any type of services to Amgen or any other type of funding not covered in the other categories will be disclosed under the "*Fee or Service and Consultancy*" category. Services generally relate to advice on Amgen pipelines or marketed products, speaker fees, speaker training, data analysis, development of educational materials, retrospective non-interventional clinical studies or consulting / advising on future Amgen programs or projects.

ToVs associated with services (expenses, like cost of travel and hotel accommodation) agreed in the written agreement covering the activity will be disclosed as under *Service-Related Expenses*.

Partnership activities between Amgen and MHCC (e.g., an HCO), under which the MHCC provides any type of service, will be disclosed in the "*Fees for Services and Consultancy*" category.

Activities not falling within the definition of R&D ToVs, including non-interventional studies (NIS) that are prospective in nature and that are not conducted to maintain a marketing authorization (in application and following definitions of the "Clinical Trials" Regulation 536/2014), will be disclosed under "*Fees for Services and Consultancy*".

COLLABORATIVE WORKING

Programs developed through collaboration or partnership of one or more pharmaceutical companies with professional societies, healthcare organizations, education providers, or other key stakeholders. The collaboration/partnership includes a commitment to a definition of mutual relationships and goals; a jointly developed structure and shared responsibility; mutual authority and accountability for success.

RESEARCH AND DEVELOPMENT

Amgen provides ToVs to HCPs or HCOs related to the planning or conduct of non-clinical studies (e.g., laboratory), clinical trials, and non-interventional studies. Research and Development ToVs in each reporting period are disclosed on an aggregated basis (without reference to names or addresses of Recipients).

Costs related to events that are considered essential to effective study conduct e.g., investigator meetings, steering committee meetings, data monitoring committees, or cost of equipments provided to study sites are included in the aggregate amount in the "*Research and Development Transfer of Value*" category.

2. SCOPE OF DISCLOSURE

2.1. PRODUCTS CONCERNED

Any ToV made in relationship with an approved Amgen medicinal product or a medicinal product in the research and development status, is in scope for reporting, set forth in *Article 1 of the Directive 2001/83/EC*, namely: (a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

2.2. COMPANY CONCERNED

Through our global systems and internal processes, we are able to reconcile all ToVs made to recipients from EFPIA countries provided by Amgen subsidiaries or affiliates across the world and consolidate into one single country report. ToVs provided through acquired companies are reported by Amgen.

2.3. EXCLUDED TRANSFERS OF VALUE

ToVs that are not listed in Section 23.05 article of the EFPIA Code of Practice, those of ordinary course purchases and sales of Medicinal Products by and between a Member Company and an HCP *(such as a pharmacist)* or an HCO do not fall within the scope of the disclosure obligation, and therefore Amgen does not report, such as:

- Sales Discounts / Rebates,
- Items of Medical Utility (governed by Article 17),
- Medical Samples (governed by Article 19), or
- Meals (governed by Article 10).

In principle, meals and drinks do not fall within the scope of the transparency obligations and should not be disclosed, but when they are an integral or inseparable part of the ToV (e.g., included in the registration fee, hotel room rate) they will not be filtered out.

National laws and codes may have additional disclosure reporting requirements or deviate from the core requirements; Amgen is committed to meeting all requirements.

2.4. TRANSFER OF VALUE DATE

Direct payments, made by Amgen through Amgen validated financial systems, will use the date the transaction was paid as the date of collection of the ToV. In case of indirect ToVs, preferably the event or meeting date is captured, where this is not possible, the payment date of the ToV to be used.

To meet reporting deadlines, Amgen will close data collection activities for ToVs made in the previous year by the end of February. Any ToVs provided after this date will be disclosed either by republishing the previous report or inclusion in the disclosure report for the following year.

2.5. DIRECT TRANSFER OF VALUE

Direct ToVs are made by Amgen through Amgen validated financial systems (e.g., SAP/ERP, Concur) directly to the in-scope recipient or service provider. There can be different dates attributed to direct payments: service provision date, invoice date, and payment date. Amgen reports direct payments based on the payment date, applying the "follow the money" principle, which can fall into a different calendar year than the service provision and/or invoice date. See the list of activity types in 2.2.

2.6. INDIRECT TRANSFER OF VALUE

Where a third-party company represents or acts on behalf of Amgen, Amgen ensures that its respective obligations are fulfilled in a written contract outlining how its obligations under the Disclosure Codes will be fulfilled. Contracts with 3rd party suppliers, who provide any ToVs to recipients on behalf of Amgen, mandate the collection of transparency-related ToVs with the required accuracy and detail. Amgen maintains oversight of outsourced activities and responsibility for disclosure reporting

Indirect payments (e.g., conference or educational support-related transfers of value where accommodation and/or travel is booked, or registration fees are paid on behalf of recipients) are either uploaded directly by the 3rd party suppliers or collected from the 3rd party supplier by the Responsible Amgen Employee (RAE) and imported into the transparency system. See the list of activity types in 2.2.

2.7. NON-MONETARY TRANSFER OF VALUE

Non-monetary benefits may be provided to POs (e.g., furniture or staff time) and reported when we are able to assign to a meaningful monetary value.

Non-monetary benefits provided to other MHCC (e.g., Items of Medical Utility to HCPs) are not reported.

2.8. PARTIAL ATTENDANCE OR CANCELLATION

Genuine last-minute cancellations of travel or accommodation made on behalf of recipients may occur due to emergency situations. Expenditure associated with such cancellations or unrecoverable spending is not attributed to the named Recipient as no ToV took place. In case of partial attendance, if possible, only related ToVs to true support are reported.

2.9. CROSS-BORDER ACTIVITIES

Through our global systems and internal processes, we are able to reconcile ToVs made to recipients from EFPIA countries provided by Amgen entities across the world.

Global and regional internal policies and procedures apply to interactions with such recipients. These procedures ensure interactions have a legitimate purpose and data is collected consistently, ensuring accuracy and capture of the required detail, regardless of the Amgen entity or the location of the interaction.

Amgen determines in which country the ToV should be disclosed based on the address where the individual has their principal practice or the entity is located, in accordance with the national law or code of that country.

ToVs collected from different Amgen entities will be reviewed by the Amgen subsidiary / legal entity responsible for the disclosure. If Amgen has no legal entity in an EFPIA country where reporting obligations apply, the Amgen legal entity with oversight of that country will conduct the data review and disclosure activity.

2.10. RESEARCH AND DEVELOPMENT

Amgen reports in aggregate, Research and Development paid to HCPs and HCOs under the category of "*Research and Development Transfers of Value*" for the following activities:

- non-clinical studies (as defined in OECD Principles on Good Laboratory Practice),
- clinical trials (as defined in Regulation N° 536/201412) or
- non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Article 18 of the EFPIA Code).

Payments reported under Research and Development can be:

- Fees for consultancy activities related to the planning/conduct of non-clinical studies, clinical trials or prospective non-interventional studies paid to HCPs or HCOs.
- Fees associated with ethics committees which review research proposals involving human participants and their data to ensure that they agree with local and international ethical guidelines.

- Costs related to events that are considered essential to effective study conduct of non-clinical studies, clinical trials, or prospective non-interventional studies i.e., Investigator Meetings, Steering Committee Meetings, Data Monitoring Committees.
- Indirect payments through Clinical Research Organizations (CROs).
- All types of medical writing related to clinical trials or related to R&D activities.
- Licensing fees paid for the use of Clinical/Health Economics and Outcomes Research questionnaires and tools (if the questionnaires and tools are intended for use with an R&D project/study).
- Ancillary services provided in hospitals (i.e., hospital services provided by non-medical staff) directly related to patient care in a trial are disclosed on an aggregate basis etc.

Research and Development activities, and in particular clinical trials, are subject to further transparency legislation under the *EU Clinical Trial Regulation (2001/20) and the European Medicines Agency Transparency Policy (Policy 0070)*. Further transparency on R&D is brough by initiatives such as the EU Clinical Trials Register and Innovative Medicines Initiative.

2.11. VOLUNTARY DISCLOSURE

Amgen does not disclose any ToVs beyond code requirements; we do not conduct any further voluntary reporting.

3. SPECIFIC CONSIDERATIONS

3.1. COUNTRY UNIQUE IDENTIFIER

In general, Amgen does not submit publicly available professional identifiers (e.g., GMC numbers in the UK). Amgen may use internal reference data and/or commercial identifiers for recipient matching, de-duplication, and quality checks before submission. Such identifiers are used for internal operational and quality control purposes and are not published. Unique Country Local Identifiers (numbers) are provided only in those countries where the Law or National Code mandates (e.g., in Spain) and where the applicable Data Privacy laws and regulations allow.

3.2. SELF-INCORPORATED HCP

Amgen recognizes that some HCPs create and work through their own companies to provide advice and services to the pharmaceutical industry. Wherever possible, Amgen identifies and publishes at the individual HCP (rather than HCO) level, as long as this can be achieved with accuracy, consistency and compliance with

applicable laws and regulations. If this is not possible, Amgen captures the name and address of the company and discloses the ToV against the company as an HCO as required by the National Codes.

According to the EFPIA Code FAQ, a self-incorporated HCP is generally an HCO, defined as "*Any legal person (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services*". If any different definition exists in a specific country, Amgen follows the National laws and regulations.

3.3. MULTI-YEAR AGREEMENTS

Amgen applies the "follow the money" principle. In case of multi-year agreements, ToVs are reported based on when payments are made to the service provider / Recipient and reported based on the payment date in the next reporting period.

3.4. COUNTRY SPECIFICITIES

SLOVAKIA

All direct and indirect transfers of value to healthcare professionals or healthcare organizations are subject to disclosure under *Act No. 362/2011 Coll. on Medicinal Products and Medical Devices*, and that were reported on the following website are not included in EFPIA deviation report.

EFPIA report includes only those transfers of value for the respective reporting year, which were not disclosed due to differences between the EFPIA definitions and local legislation.

UK

Where Amgen participates in UK activities together with one or more pharmaceutical companies, responsibility for disclosure is determined in accordance with the contractual arrangements between the participating parties and the applicable *ABPI Code* requirements. Amgen discloses the Transfers of Value for which it is responsible and, where relevant, only the proportion attributable to Amgen. Where a collaborative working executive summary is required for a UK activity, the relevant executive summary is published separately and the applicable link is included in the relevant UK disclosure materials.

3.5. QUALITY CHECKS

Amgen utilizes an externally hosted Managed Service (MS) provider and system for the collection and review of ToVs and report generation to comply with its law and code-based reporting obligations in all jurisdictions. The MS provider performs several pre-disclosure quality checks before the final reports are provided to the relevant disclosing countries or Amgen affiliates.

4. CONSENT MANAGEMENT

4.1. COLLECTION OF CONSENT

Amgen obtains consent from each HCP and HCO, where required by the applicable Local Data Protection Law/Regulation, to disclose their personal data, in a manner that meets the applicable legal requirements for valid consent and is documented, either via specific disclosure clauses in the contract, a separate consent statement or a consent statement in an invitation letter. Where disclosures are required under the applicable Local Data Protection Law/Regulation, or where the National Data Protection Authority provides an exemption/authorization or where disclosures are conducted in the country based on the legitimate interest approach, consent will not be required. In countries where disclosures on an individual basis are subject to appropriate consent; where such consent cannot be secured, related ToVs will be disclosed in aggregate.

4.2. LEGITIMATE INTEREST

Amgen relies on Legitimate Interests as the lawful basis for the processing and publication of individual HCP/ORDM (other relevant decision makers) ToV on Disclosure UK. Amgen applies a Legitimate Interests assessment, including a balancing test, to determine whether named disclosure is necessary and proportionate for transparency purposes and whether those legitimate interests outweigh the interests, rights, and freedoms of the individual.

Amgen provides relevant privacy information to HCPs/ORDMs and informs them of the disclosure process and their right to object. Any objection is assessed on a case-by-case basis, considering the reasons raised and the individual's particular situation. Objections are not treated as an automatic opt-out. Where appropriate, Amgen reassesses the balancing test before determining whether individual publication should proceed in accordance with the applicable UK disclosure requirements.

5. FORM OF DISCLOSURE

5.1. DATE OF PUBLICATION

Disclosures are made within 6 months after the end of the relevant reporting period, set during the time interval from 20th to 30th June each year at the latest, or earlier as required by the National code, and the information remains in the public domain for 3 years after the time such information is first disclosed. Where the National Code provides a different time interval for its country, Amgen follows this different time interval consistently.

5.2. DISCLOSURE PLATFORM

Amgen discloses ToVs in two ways depending on the Law or National Code requirements in each country:

- via central platforms when available / implemented by the National Industry Association or regulatory body in the country and/or
- on Amgen external website (local or corporate).

Amgen's corporate website www.amgen.com is utilized for disclosure reporting in countries where Amgen does not have a legal entity (and/or an own external facing website: Bosnia-Herzegovina, Cyprus, Estonia, Iceland, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Serbia, and Ukraine).

Amgen also discloses its EFPIA Patient Organizations reports on the Amgen corporate website.

In the event that Amgen has more than one legal entity in a country, disclosure reports are published on one single Amgen website in that country (or on the same central platform) for ease of access.

The Amgen European Gateway provides links to each country's disclosure report/platform and their National Association website.

5.3. DISCLOSURE LANGUAGE

Amgen will make reports available in the language(s) required by Law or National Code.

6. DISCLOSURE FINANCIAL DATA

6.1. CURRENCY MANAGEMENT

Amgen collects ToVs in the original currency, in which they were made. The national disclosure report will present ToVs in the country's national currency. Exchange rates are based on approved currency exchange rates used by the Amgen validated financial system of record.

6.2. TAX MANAGEMENT

Amgen reports ToVs as net, e.g., without value added tax (VAT) or withholding tax (WHT) – unless the Legal or National Disclosure Code requirements state differently, or the collection of net values is not possible through Amgen financial systems of record or third-party processes.

6.3. OTHER CALCULATION RULES

When Amgen provides non-monetary / non-financial support to a Patient Organization (e.g., old furniture donation), and even if this support does not cost anything to Amgen, we calculate and report publicly the available value for a comparable or similar product.

In the UK, benefits in kind or services freely given to members of the healthcare community, including patient organizations, are in scope of disclosure. The value of the ToV is determined based on the fair market value of the items or services provided.

7. ADDITIONAL INFORMATION

7.1. MANAGING CONSENT WITHDRAWAL

Amgen has a well-established internal process to manage withdrawal requests within the timelines required by the Local Data Protection Law/Regulation. The withdrawal request must be submitted by HCPs, via available means, including contacting the Responsible Amgen Employee (RAE) / Amgen Contract Signee, the Amgen Compliance Privacy Team at privacy@amgen.com or via Amgen´s privacy webform.

Where consent is required, HCPs (and where relevant HCOs) can withdraw their consent for the individual disclosure of their information at any time. Where their consent is withdrawn or not provided, Amgen will disclose all ToVs made to them on an aggregate basis that does not identify them.

7.2. MANAGING DATA PRIVACY REQUEST

In accordance with Local Data Protection laws/regulations, a Recipient may request a copy of the information Amgen holds about them, including the information on ToVs which the company may publish against their name. A Recipient can request data - they believe to be inaccurate - be corrected. In such cases, Amgen will follow its internal processes to check and verify the identity of the Recipient and the accuracy of the data before making any necessary adjustments to its public disclosure reports.

To access their data, a Recipient can contact Amgen via the contact details mentioned in their contract or by contacting the Compliance Privacy Team via e-mail: privacy@amgen.com or via Amgen´s privacy webform. Amgen will follow its internal processes to ensure all requests to access personal data are handled within the timelines required by the relevant Data Protection authorities.

7.3. PARTIAL CONSENT

If a Recipient gives only partial consent to any aspect of disclosure e.g., the Recipient does not allow disclosure of all categories or of all ToVs, Amgen discloses all ToVs made to that Recipient in the aggregate category for the entire reporting period (calendar year), consistent with applicable local requirements. Partial disclosure under the individual category would be misleading with respect to the nature and scale of the interaction between Amgen and the HCP or HCO and would not fulfil the intent of transparency through disclosure.

DOCUMENT HISTORY

Version	Summary of Change	Description of the Chage
6.0	The new standardised structure applied to the Amgen Methodological Note document.	On the 20th of March 2025, the EFPIA Board approved a new template for the Methodological Note including common terminologies and layout.
5.0	Scope update, link updates, clarification for Ethics Committees, reference to PCOs, European Gateway link.	SCOPE: Extended the list with the "membership fees" and updated the Link. 4.7.2 Ethics Committees' disclosure clarified. 5.3 Under Sponsorship Agreements reference made to POCs. 5.4 Partnership activities' place of reporting added. 7.2.1 European Gateway reference added.
4.0	No content change in the document. The document type changed from "Internal Use Only" to "Public".	The document type changed from "Internal Use Only" to "Public".
3.0	Section 8.0 "EXCEPTIONAL HANDLING OF TOV DUE TO THE PANDEMIC" renamed to "COUNTRY NATIONAL DISCLOSURE CODE / LAW"	Removed "Exceptional Handling of ToV Due to the Pandemic" and renamed to allow capturing specific country requirements.
2.0	Section 8.0 Exceptional Handling of ToV Due to the Pandemic added	New section added which included details of Amgen business activities impacted by COVID-19.
1.0	Amgen's Methodological Note	Initial document