Methodological Note

EFPIA & Local Industry Association Disclosure Codes

1.0 INTRODUCTION

Amgen is committed to transparent interactions with Healthcare Professionals (HCPs), Healthcare Organisations (HCOs) and Patient Organisations (POs). 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.

HCPs, HCOs and POs are the primary point of contact with patients, they offer expert knowledge on patients' behaviour 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. We compensate HCPs, HCOs and POs for the valuable insights and time they offer, we also provide funding for medical education either directly to HCPs, via HCOs or third-party specialist providers.

Disclosing Transfers of Value (ToV) such as payments and other benefits e.g. travel, and accommodation costs we make to HCPs, HCOs and POs will enhance the public understanding of why interactions are necessary to improve patient care. The pharmaceutical industry associations in each EFPIA country have introduced disclosure requirements into industry codes or countries have implemented laws on disclosure, Amgen will comply with the Codes or laws applicable in each country we operate; conducting business with strong ethical principles and with the strictest integrity.

In line with the code or legal requirements, Amgen will publicly disclose the ToV it makes to HCPs, HCOs and POs (hereafter 'Recipient').

In this document (hereafter 'Note') Amgen summarizes the methodologies used to prepare the disclosures and identify ToV.

2.0 SCOPE

This Note applies to the 36 countries[1] who are members of the European Federation of Pharmaceutical Industries & Associations (EFPIA) and Luxembourg where Amgen has interactions with Healthcare Professionals or Healthcare Organisations.

Amgen discloses any support provided to Patient Organisations (e.g. donations, grants, payment for consulting services etc.) in accordance with the EFPIA Code of Practice. Latest disclosure reports can be found here Link.

Support provided by the Amgen Foundation[2] can be found here Link.

[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, North Macedonia, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom.

[2] The Amgen Foundation seeks to advance excellence in science education to inspire the next generation of innovators and invest in strengthening communities where Amgen staff members live and work.

3.0 DEFINITIONS

Link to the **EFPIA** Code of Practice to learn more about the code, its definitions and the general reporting requirements.

4.0 DATA COLLECTION FOR DISCLOSURE & IDENTIFICATION OF RECIPIENTS

4.1 HOW AMGEN COLLECTS AND PROCESSES DATA

4.1.1 DATA COLLECTION

Transfers of Value (ToV) to a Recipient in an EFPIA country can be provided by any Amgen entity across the world.

Global and regional internal processes apply to interactions with such Recipients. These processes 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.

ToV can be provided:

- Directly by Amgen to Recipients e.g. payments for services HCP/HCO/PO provided to Amgen, or
- Indirectly by 3rd Parties e.g. accommodation, travel or registration fees for HCPs to attend medical education events.

Contracts, with 3rd parties who provide any ToV to HCPs, HCOs or POs on behalf of Amgen, mandate the collection of transparency related ToV with the required accuracy and detail; Amgen maintains oversight of outsourced activities and responsibility for disclosure reporting. In principle, meals and drinks do not fall within the scope of the transparency obligations (exceptions may exist) 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.

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

For ToVs to HCPs and HCOs, transactions 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 a particular EFPIA country, the Amgen entity with oversight of that country will conduct the data review and disclosure activities. For ToVs to POs, all transactions are reviewed by the Amgen entity making the ToV. Refer to the 'REPORTING' section for more information.

4.1.2 DATE USED FOR DATA COLLECTION

Direct payments made by Amgen, generated through our financial system, will use the date the transaction was paid as the date of collection of the ToV. This approach is applicable to single and multi-year contracts which may result in multiple ToV.

In case of indirect payments (e.g. conferences where accommodation and/or travel is booked, or registration fees are paid on behalf of Recipients) all relevant expenses are collected from our 3rd Party Suppliers and imported into the Amgen data collection system. Preferably the conference or meeting date is captured as the date of collection of the ToV, where this is not possible the payment date of the ToV is used.

Amgen will collect ToV for services both provided and paid as of 1st January each year and will report within the first 6 months of the following year or earlier as required by specific countries. To meet reporting requirements Amgen will close data processing activities for ToV made in the previous year by the end of February. Any ToV processed after this date will be disclosed either by republishing the previous report or inclusion in the disclosure report of the following year.

4.1.3 TAX

Amgen reports ToV as net, e.g. without value added tax or withholding tax – unless the Disclosure Code / Legal requirements of a country state differently or the collection of net values is not possible through Amgen financial systems.

4.1.4 CURRENCY MANAGEMENT

Amgen collects ToV in the original currency in which they were made. The national disclosure report shows ToV in the country's own currency. Exchange rates are based on the approved currency exchange rates used by Amgen's validated financial systems and procedures which are subject to external inspection by independent auditors.

4.1.5 UNIQUE IDENTIFIERS

Unique Country Local Identifiers (numbers) are provided in those countries where the local code or law mandates, and where the applicable data privacy laws and regulations allow.

4.1.6 IF PLANNED TRANSFER OF VALUE DOES NOT TAKE PLACE

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 spend is not attributed to the named Recipient as no ToV took place.

4.2 IDENTIFICATION OF RECIPIENTS

4.2.1 CLEARLY IDENTIFIABLE RECIPIENT AND COUNTRY

Amgen has internal processes to ensure all ToV made to Recipients are collected and reconciled in Amgen data collection and review tools. Amgen utilises both an internal and a proprietary commercial database from which both name and preferentially business address are taken for disclosure. If a Recipient cannot be found in the proprietary commercial database Amgen will capture the required information for disclosure in its own database. These processes allow us to identify the Recipient of the ToV and ensure disclosure in accordance with code (or legal) requirements.

4.2.2 CROSS-BORDER PAYMENTS / TRANSFERS OF VALUE

Amgen operates globally, our entities across the world have interactions with Recipients in EFPIA countries. Through our internal processes and systems, we are able to reconcile ToV made to Recipients from EFPIA countries provided by Amgen entities across the world. Amgen's data collection and review tool receives transactions from the various Amgen entities and reconciles them i) for HCPs and HCOs - based on the country where the Recipient conducts business and where they will be reported. Quality checks are performed by the Amgen reporting entity; and ii) for POs - based on the country where the Amgen entity making the ToV is located. Quality checks are performed by the Amgen entity where the PO is located.

4.2.3 PAYMENTS / TRANSFERS OF VALUE MADE BY 3RD PARTIES ON BEHALF OF AMGEN

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.

4.2.4 EDUCATION OF HCPs THROUGH HCOs and POs

If Amgen provides ToV for medical education of HCPs through a HCO or PO, we will disclose the ToV against the HCO or PO. If Amgen selects the individual HCPs who benefit from the educational event conducted by the HCO or PO, we will disclose individually under the name of each HCP if they have provided consent under the relevant data privacy law. Refer to section 6 for more information.

4.2.5 UNIVERSITIES AND TEACHING INSTITUTIONS

ToV will be disclosed under the university or teaching institution which is the Recipient of the ToV if Amgen support or involvement benefits a HCP/HCO.

4.2.6 HEALTHCARE PROFESSIONALS WHO OPERATE THROUGH THEIR OWN OR THIRD-PARTY COMPANIES

Some HCPs create their own company or work through a company to provide advice and services to the pharmaceutical industry. Amgen will capture the name and address of the company and disclose the ToV against the company as an HCO as required by the Codes.

4.2.7 CLINICAL RESEARCH ORGANISATIONS & ETHICS COMMITTEES

A Clinical Research Organisation (CRO) is an organisation 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 healthcare organisations (HCOs), however if Amgen makes ToV to HCPs/HCOs through CROs Amgen will disclose the indirect ToV in the relevant disclosure category.

An Ethics Committee is designated to approve, monitor, and review biomedical and behavioural research involving humans. Amgen will never make payments to HCPs individually via an Ethics Committee.

5.0 CATEGORIES OF DISCLOSURE

5.1.1 DONATIONS AND GRANTS

Amgen provides Transfer of Value (ToV) as Grants or Donations to Recipients (not for profit HCOs and Patient Organisations) 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 are formalised in contracts that describe the purpose of the donation and the related ToV. If a 'donation in kind' is provided to a Recipient e.g. Amgen staff time, a monetary value will be attributed to the 'in kind' donation for the purpose of disclosure.

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

Patient Organisation reports detailing ToV provided are published centrally on Amgen's corporate website (www.amgen.com).

5.1.2 CONTRIBUTION TO COST OF EVENTS

Amgen provides ToV to Recipients for educational support at medical/educational events or congress for:

- TRAVEL AND ACCOMMODATION

Including the cost of flights, trains, car hire, tolls, parking fees, taxis and hotel accommodation, etc.

- REGISTRATION FEES

The cost of registration fees for a Recipient to attend a medical / educational event or congress.

5.1.3 SPONSORSHIP AGREEMENTS WITH RECIPIENTS / THIRD PARTIES APPOINTED BY RECIPIENTS TO MANAGE AN EVENT

Amgen provides ToV when sponsoring a Recipients event or project. Where a third-party company is a conference or event organiser acting on behalf of a Recipient Amgen will make every effort to disclose ToV against the beneficiary Recipient(s) even when the payment is made to the third-party company. Agreements are formalised in contracts that describe the purpose of the sponsorship, the benefits Amgen receive and the related ToV. If the sponsorship includes registration fees, travel and accommodation, these will be disclosed separately in the relevant categories in the name of the HCO/ PO, unless the recipient HCP is known to Amgen whereby we will disclose against the individual if we have the necessary consent. Agreements generally relate to rental of booth space, advertisement space, drinks and meals provided by the event organizer and satellite symposia at a medical / scientific congress.

Where an event is organized by multiple HCOs/ POs cost will be apportioned accordingly.

5.1.4 FEE FOR SERVICE AND CONSULTANCY

Amgen provides ToV for services Amgen receives from Recipients under service agreements. Services generally relate to advice on Amgen pipeline 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. These will be disclosed in the relevant HCP/HCO and PO reports. Cost of travel and hotel accommodation associated with services Amgen receive will be disclosed under “Service Related Expenses” in the HCP/HCO disclosure reports.

5.1.5 RESEARCH AND DEVELOPMENT TRANSFERS OF VALUE

Amgen is an innovative company with compounds in early research and products in development undergoing clinical trials. We provide ToV to HCPs or HCOs related to the planning or conduct of non-clinical studies (e.g. laboratory), clinical trials and non-interventional studies[3].

[3] Non-Interventional Studies are designed to answer specific questions about a new drug treatment when its prescribed by a HCP to a patient.

Research and Development ToV 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 are included in the aggregate amount in the "Research and Development Transfer of Value" category.

Amgen will not publish any information what would be seen as commercially sensitive, in compliance with relevant laws and regulations.

6.0 DATA PRIVACY / PROTECTION: HCPS (AND HCOS AS REQUIRED)

6.1.1 MEETING DATA PRIVACY REQUIREMENTS

Data privacy laws exist to protect the personal information of individuals, these laws apply to HCPs in all countries and HCOs e.g. Austria and Luxembourg. To ensure Amgen comply with data privacy laws we require HCPs (and where relevant HCOs) consent to Amgen collecting, processing and publishing summary details of the Transfer of Value (ToV) we make during our interactions. If disclosures are required under local law consent will not be required.

Amgen has internal processes to ensure personal information is secure and protected in accordance with all applicable laws.

6.1.2 CONSENT PROCESS

Amgen will obtain the consent, as required, of each HCP (or HCO where required by local privacy laws) to disclose their personal data primarily via data protection, privacy and disclosure clauses in a contract, via a separate consent statement or via a consent statement in an invitation letter supported by a signing in roster of attendees to the event.

6.1.3 AGGREGATE DISCLOSURE

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 ToV made to them on an aggregate basis that does not identify them.

If an HCP (or HCO, where applicable) gives only partial consent to any aspect of disclosure, all ToV Amgen made to that HCP (or HCO where applicable) will be disclosed in the aggregate category for the entire reporting period (calendar year), subject to applicable laws.

Partial disclosure under the individual category would be misleading with respect to the nature and scale of the interaction between Amgen and the HCP (HCO), and would not fulfil the intent of transparency through disclosure.

6.1.4 RECIPIENTS ACCESS TO THEIR DATA

In accordance with national privacy laws a Recipient, may request a copy of the information Amgen holds about them, including the information on ToV 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 with Amgen or by contacting our Global Privacy Office via e-mail: privacyoffice@amgen.com. Amgen will follow its internal processes to ensure all requests to access personal data are handled within the timelines specified by the relevant country data protection authorities.

7.0 REPORTING

7.1 QUALITY CHECKS PRIOR TO REPORTING

Prior to reporting, Amgen internal processes ensure Transfer of Value (ToV) made to Recipients are collected and reconciled in Amgen data collection and review tools. Data quality checks are performed to ensure any HCP (HCO as appropriate) who has not provided consent for individual disclosure are reported in 'aggregate', additional data and process monitoring takes place for quality assurance prior to reporting.

All ToV to an HCP / HCO will be reported in the country where they conduct their main business irrespective of where the interaction occurred. All ToVs to POs will be reported under the Amgen affiliate making the ToV.

7.2 LOCATION OF DISCLOSURE REPORTS

7.2.1 PLATFORMS

Unless an EFPIA approved exception applies Amgen discloses ToV in two ways depending on the Code or legal requirements of each country:

- on Amgen external webpages and/or
- via central platforms implemented by local industry associations or regulatory bodies in a specific country.

Amgen external webpages are the locations of the disclosure reports in the following countries: Austria, Bulgaria, Croatia, Finland, Germany, Greece, Hungary, Italy, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Switzerland, and the Netherlands.

Amgen's corporate external website (www.amgen.com) will be utilised for disclosures where Amgen does not have a legal entity, like Bosnia-Herzegovina, Cyprus, Estonia, Iceland, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Serbia and Ukraine. Amgen will also disclose ToV to recipient HCPs and HCOs in Luxemburg and ToV's to POs on this corporate site.

Amgen publishes ToV made to recipient HCPs and HCOs on central platforms in following countries: Belgium, Czech Republic, France, Ireland, Portugal, Romania, Slovakia, Sweden, the Netherlands and UK.

In the event that Amgen has more than one business in a single country ToV are disclosed on a single Amgen webpage in that country (or on the same central platform) for ease of access.

7.2.2 LANGUAGE OF DISCLOSURE REPORTS

Amgen will make reports available in the languages required by each local code or law.

8.0 EXCEPTIONAL HANDLING OF TOV DUE TO THE PANDEMIC

During the COVID-19 Pandemic, Amgen and it's staff remained fully committed to Code of Practice, regulatory and legal requirements. We continued to implement the highest ethical standards and practice best efforts whilst assessing the appropriateness of activities and putting patients first. In the event of a conflict of guidance, the more restrictive requirement was applied.

Due to exceptional circumstances, numerous business activities and interactions were impacted by COVID-19 which resulted in limitations within meetings, congress, sponsorships, exhibits and donations, some activities were cancelled or postponed.

Donations underwent significant process changes in order to fulfil urgent requests to provide funding related to the COVID-19 crisis. Due to the urgent nature of these donations, Amgen developed an interim 'quick response' procedure to track COVID-19 related Donations for all countries, managing the process and maintaining compliance. When the urgency subsided, donations were entered into Amgen's compliance system of record.

Due to the pandemic, Amgen adapted how we conduct our interactions and engagements: travel and in-person interactions with Healthcare Professionals were prohibited and, if appropriate, conducted virtually.

In line with guidance, no meals, drinks or hospitality were provided to individual members of the Healthcare Community attending a virtual Amgen organized meeting, third party organised meeting or 1:1 discussion. Where an Event was cancelled due to COVID-19, the ToV related to the event was disclosed where it could be attributed to a recipient. Where an Event was cancelled and no ToV occurred, no disclosure took place. Where an Event was converted from face to face to virtual and the recipient received a ToV (e.g. virtual registration) this was disclosed.

Amgen is mindful of the additional challenges and workload Healthcare Communities' have undertaken and have respected the changing priorities of HCPs during this time. Due to exceptional circumstances, if Amgen did not clearly receive consent (if required) to disclose individually we have disclosed ToV's in aggregate, as a result levels of consent have been impacted.

9.0 RELATED REFERENCE DOCUMENTS

EFPIA for the **National Member Associations' Codes** of Practice on the promotion of prescription-only medicines to, and interactions with, healthcare professionals and healthcare organizations: Link.

10.0 DOCUMENT HISTORY

Version	Summary of Changes	Change Summary
1.9	Section 8.0 no longer covers Country National Disclosure Code/ Law specifics, this has been replaced with Exceptional Handling of Tov Due to The Pandemic.	Exceptional Handling of ToV Due to The Pandemic. Includes details of Amgen business activities that were impacted by COVID-19. Country National Disclosure Code/ Law specifics have been removed from the core Methodological Note and where required are presented as an addendum.
1.8	Section 8.0 Country National Disclosure Code/ Law specifics	Amendments to Country National Disclosure Code/ Law specifics
1.7	Section 8.0 Country National Disclosure Code/ Law specifics	Amendments to Country National Disclosure Code/ Law specifics- Joint Working Summaries
1.6	Inclusion of reference to Patient Organisations where applicable. Update reference to EFPIA Code of Practice. Update to the list of countries in scope of EFPIA disclosure and the location of their reports Section 8.0 Country National Disclosure Code/ Law specifics Section 9.0 Related Reference Documents	Included reference to POs when wording also applies. Disclosure Code consolidated into EFPIA Code of Practice Disclosure reports for Bosnia-Herzegovina and Macedonia will be created as required. Addition of an entry for Ireland to cover the reporting of Joint Working type initiatives. Edit to the existing Slovakian entry to provide clarity on disclosures made to comply with EFPIA requirements. Addition of explanatory text to the UK entry to provide insight into the exceptional approach to disclosure of 2019 ToV during the COVID-19 pandemic of 2020. Joint Working detail and weblink added. Updated link to National Member Associations' Codes of Practice.
1.5	Section 8.0 Country National Disclosure Code/ Law specifics Section 7.2.1 Platforms	Minor edit to remove reference to 2017 (Spain). Minor rewording of first sentence.
1.4	Section 8.0 Country National Disclosure Code/ Law specifics	Entries for Belgium, Italy, Romania, Spain & Slovakia added. Entries for Czech Republic & Greece edited to reflect clarifications on definitions and the scope of individual and aggregate

Version	Summary of Changes	Change Summary
		disclosure reporting respectively.
1.3	Section 4.1.2 Date used for data collection	Minor edit regarding disclosure of data captured after close of data processing activities for the reporting period.
1.2	Section 7.2 Location of Disclosure Reports Section 8.0 Country National Disclosure Code/ Law specifics	Minor edits made to ensure the section accurately reflects where disclosures are made. Entry for Greece amended to reflect that disclosures of ToV for HCP's will be made in aggregate and will not currently distinguish between Type A and Type B events (alignment of SFEE member companies).
1.1	Section 9.0 Related reference documents	Updated link to the EFPIA webpage
1.0	Amgen's Methodological Note	Initial document

SWITZERLAND: NATIONAL DISCLOSURE CODE / LAW SPECIFICS

Art. 133 and 134 Swiss Pharma Cooperative Code:

Differences in the scope of definitions for HCPs and HCOs.