Methodological Note for HCP/HCO/PO Disclosure Data Year 2025

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Introduction

Collaborative working between medical professionals and healthcare organizations has long been a positive driver for advancements in patient care and the development of innovative medicine. Medical professionals and the organizations with whom they work provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and disease management experience. Furthermore, as the primary point of contact with patients, the medical professional can offer valuable expert knowledge on patient outcomes and therapy management. This helps to adapt our products to better suit patients and thereby improve patient care overall.

Healthcare professionals and organizations should be fairly compensated for the services they provide to pharmaceutical companies. The EPFIA Disclosure Code ("Code") provides accuracy and transparency in disclosing the scope and value of such collaborative work, and it will become an important step towards building greater trust between the pharmaceutical industry, medical community and patients.

As a member company of de Vereniging Innovatieve Geneesmiddelen ("VIG") and as a full corporate member of EFPIA, AstraZeneca ("AZ") is committed to transparency around interactions with Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs) and that these are captured and reported in line with all applicable local transparency requirements.

The aims of the EFPIA Disclosure Code and its local interpretation in the CGR Code of Conduct – to promote ethical and transparent interactions with the Healthcare community – are fully aligned with AZ's own policies. Interactions with HCP/HCOs are governed by the AZ Global Standards, including zero tolerance for giving or receiving anything of value that is intended or could be seen as improper influence.

Producing transparency reporting is an opportunity for AZ to demonstrate its commitment to the values and principles behind the EFPIA Disclosure Code and other transparency requirements in Europe.

The objective of this note is to explain AZ's approach to disclosure, to include key definitions, the scope of disclosed activities and key elements of the process followed to capture and report data.

At a high level, there are three main tenets that characterize the AZ approach:

(1) Affiliate accountability and regional consolidation
Affiliates are responsible for capturing the Transfers of Value (ToVs) made in their affiliates and for validating the accuracy of the data. A regional reporting solution consolidates the ToVs, providing consistency and automating inclusion of cross border payments within Europe. Other cross border payments are collected through a payment system (US) or manually (rest of world).

(2) Compliance with local codes
Unless there are strong legal mandatory requirements, affiliates have transposed the Code in full i.e. without deviations. In each country, AZ will comply with applicable local disclosure

requirements. There may be variations (stricter than the provision in the Code) or deviations (where because of mandatory national regulations the Code cannot be transposed in full).

(3) One disclosure per market, including all ToVs paid directly through entities belonging to AZ or indirectly through third parties acting on behalf of AZ

For the Netherlands, disclosure is made in a central transparency register, set up in collaboration with the Ministry of Health, Welfare and Sport: 'Transparantieregister Zorg'.

Disclosure is compulsory if the Health Care Professional, partnership or institution in question receives more than EUR 500 from a pharmaceutical company in any calendar year.

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1 Definitions

Healthcare Professionals are abbreviated as **HCPs** in the following report.
Healthcare Organisations are abbreviated as **HCOs** for reporting.
Patient Organization is abbreviated as **PO** in the following report.
Benefits relevant to reporting are abbreviated as **ToVs** in the following report.

1.1 Recipients

1.1.1 Definition of an HCP

The definition of an HCP in the Netherlands is:

A person qualified to prescribe or supply prescription-only medicinal products.

Publication is determined by the recipient's active status in BIG Register when the disclosure is published, regardless of the later HCP status changes, e.g. retirement or job change. If AZ NL becomes aware of the HCP death, the HCP will be removed from the disclosure report.

1.1.2 Definition of an HCO

The definition of an HCO in the Netherlands is:

Partnerships of healthcare professionals and institutions which employ healthcare professionals.

1.1.3 Definition of a PO

A non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe.

1.2 Kind of ToVs

1.2.1 Donations and Grants

AZ provides support to advances in medical or scientific research and healthcare or healthcare systems through financial or non-financial ToVs to legitimate, established organisations.

AZ can provide this support through:

- Contributions or funding (also referred to as Grants) to support initiatives in Medical or Scientific Research as well as Projects supporting healthcare.

In the Netherlands' CGR Code, such kinds of initiatives are defined as "Sponsorship of projects".

- Donations to a non-profit or public sector healthcare organization (HCO) intended to support their charitable mission and activities. Donations and grants to Patient Organizations are included, donations and grants as part of Community Investments to charities and other non-profit non-HCOs are subject to separate disclosure and thus excluded.

Donations to HCOs can be both monetary and donations in kind. Product donations are given in circumstances of national emergency, international or national disaster relief or other genuine public health need. AZ charitable product donations and processes are aligned to the World Health Organisation (WHO) Guidelines for Drug Donations.

1.2.2 Sponsorship of Events

AZ gives contributions, through financial or non-financial support to legitimate, established organizations for medical or scientific education of external stakeholders, organizing or hosting educational or scientific events (including independent congresses). These contributions aim to increase the scientific or educational quality of the event and/or support with logistics in modest venues or with incidental hospitality, in line with AZ's own ethical principles. The mandatory Sponsorship Agreements will describe the purpose of the sponsorship and for what the funds are to be used.

Sponsorship packages may also include satellite symposia and the sponsoring of speakers or faculty.

ToVs are made to either the HCO directly or to an event organizer or other third party appointed by the HCO to manage the event. In all cases, ToVs are disclosed against the HCO that ultimately benefits.

Where contributions made to HCOs include support for travel & accommodation for HCPs to attend Independent Congresses and the HCPs benefitting from this support are unknown, this payment will be assigned to the EFPIA category "Sponsorship of Meetings".

1.2.3 Registration Fees

As part of support to continuous medical education, AZ provides support to HCOs or HCPs to cover the costs of registration fees for HCPs to attend selected independent congresses and where provided to HCOs, also for other educational/scientific events.

Where these are provided to HCOs, AZ is not involved in the selection of the HCPs.

Where these are provided to individual HCPs, the purpose of the support is to enable delegates:

- to attend presentations or participate in scientific exchange on significant developments related to AZ products or uses or related to AZ's scientific research; or,
- to support the performance of a contract.

All arrangements are generally paid directly to travel and/or accommodation providers or organizer.

1.2.4 Travel and Accommodation

As part of support to continuous medical education, AZ provides support to HCOs or HCPs to cover the costs for Travel and Accommodation for HCPs to attend selected independent congresses and/or AZ Organized Meetings and where provided to HCOs for other educational/scientific events.

These costs can include costs of flights, trains, hotel accommodation, taxis, bus transfers, and other travel costs.

Costs for ground transportation (e.g. bus or taxi) that are organized for group transportation and not assigned to certain HCPs are reported in aggregate, but where the identity of the HCPs is known, these are split by HCP.

1.2.5 Fees for Service and Consultancy and Related Expenses

AZ engages an HCP/HCO/PO for services when there is a genuine and legitimate business need and where the HCP/HCO/PO is qualified and appropriate to provide the services. These services are paid with a Fee for Service at Fair Market Value.
These services can include:

- Speaking at and chairing meetings
- Training services
- Participation in advisory board meetings
- Medical writing
- Data analysis
- Development of education materials
- General consulting/advising
- Services performed in connection with a third-party congress
- Retrospective non-interventional studies
- Participation in market research where such participation involves remuneration and/or travel. Payments for these services are only disclosed if AZ is aware of the identity of those participating in the market research.

As part of the written Fee for Services Agreement, related expenses can be paid for and can include costs of flights, trains, car hire, tolls, parking fees, taxis, bus transfers, hotel accommodation, visa costs and hospitality costs. All costs are paid by AZ to travel and/or accommodation providers or meeting organizers (where relevant) or reimbursed supported by appropriate receipts.

1.2.6 Research and Development

All ToVs related to the planning or conduct of non-clinical studies, clinical trials and non-interventional studies performed by AZ or by Clinical Research Organizations on AZ's behalf that

are prospective in nature are considered Research & Development ToVs and are reported on an aggregate basis.

ToVs related to R&D activities can include the following:

- Science Units are separate entities within AZ and perform non-clinical studies (as defined in OECD Principles on Good Laboratory Practice) and clinical trials (as defined in Directive 2001/20/EC). Where Science Units have made ToVs to HCPs or HCOs, these have been considered to be related to R&D activities. Events or consultancy fees in relation to R&D are also reported in the aggregate.
- Costs related to events that are clearly related to activities covered by the R&D ToV (e.g. clinical investigator meetings, Steering Committee meetings for a specific clinical trial).

Retrospective non-interventional studies or other studies that are not submitted to authorities as per local drug law do not fall under the category of R&D activities.

1.2.7 Hospitality Costs

AstraZeneca discloses the value of any hospitality costs related to:

1) International congresses for both HCP speakers and attendees
2) Consulting services, advisory board or steering committee meetings, and other events where the HCP provides a service and receives hospitality.

The value of meals provided is determined by dividing the total cost of the meal by the total number of participants in the meal. Participants may include physicians, mid-level practitioners' medical staff, and AstraZeneca representatives.

The value of hospitality provided during local educational meetings is excluded from disclosure for speakers or service providers as well as attendees.

2 Disclosure's Scope

2.1 Products concerned

AZ is a science focused company, developing innovative medicines that are prescription only medicines and interactions with HCPs/HCOs/POs are focused on the development and promotion of prescription medicines. Consequently, only ToVs relating to prescription medicines are being disclosed.

2.2 Company concerned

The report covers the disclosure of transfers of value to HCPs, HCOs and POs that practice or are registered in the Netherlands that are provided by AstraZeneca Netherlands, its affiliates and acquired or merged companies (if not disclosed under the acquired company name separately) irrespective of their location.

2.3 Excluded ToVs

2.3.1 Informational and educational materials and items of medical utility

As per Section 1.02 of the EFPIA Disclosure Code, items of medical utility for HCPs and informational and educational material are not disclosed where in line with Art 9 of the HCP Code which states that "The transmission of informational or educational materials is permitted provided it is: (I) “inexpensive”; (II) directly relevant to the practice of medicine or pharmacy; and (III) directly beneficial to the care of patients".

2.3.2 Donations to charitable organisations

All ToVs to non-HCO organizations are out of scope and excluded, e.g. charitable organizations.

2.3.3 Logistical costs

Logistical costs related to AZ Organized Meetings (e.g. room hire, technics, personnel) are excluded. However, ToVs to participants, such as support for travel and accommodation or speaker fees to HCPs are included in the relevant cost category.

2.4 ToVs date

Where the ToV is a payment, values are reported on the date of the payment i.e. the date the funds are transferred to the recipient's bank account. Payments made in 2024 for activities related to 2023 are included.

Where ToVs relate to multi-year contracts, only the ToVs made in the reporting year are included. Where the ToV is a benefit in kind, values are reported on the date the recipient received the benefit.

2.5 Direct ToVs

The natural or legal person that holds the bank account on which the money is transferred is considered the recipient of the ToV and will be disclosed.

Direct ToVs are captured in SAP and flow into AZ transparency reporting system based on their vendor code, General Ledger code and activity code. They are then mapped to the appropriate activity category in line with local association guidelines for reporting. In the case of direct ToV transactions that are made outside of the EFPIA member countries, these are uploaded to the transparency system via a manual template (based on actual payment data in another SAP system).

2.6 Indirect ToVs

2.6.1 Indirect ToVs through CROs

Where a Clinical Research Organization acts on behalf of AZ to make ToVs to HCPs/HCOs, these are within the scope of the Disclosure and are reported at an aggregate level under R&D as long as their activities fall within the scope of the definition of R&D activities.

2.6.2 Indirect ToVs through other third parties

Where third parties are appointed by an HCO to manage an event, and where the HCO ultimately benefits from that ToV, these ToVs are disclosed against the HCO. Where an event is organized on behalf of multiple HCOs without clarity on allocation, the value is divided equally between the HCOs.

Where third parties are appointed by AZ to make travel and accommodation arrangements for HCPs who are providing services or are supported to attend events, these ToVs are disclosed against the HCP.

Any additional administration fees charged by agencies are not included, as these are not ToVs to HCPs or HCOs.

2.6.3 Indirect ToVs through HCOs

Where ToVs are made to an individual HCP indirectly via an HCO will be disclosed against the HCP in line with local association guidelines.

2.7 Non-monetary ToVs

Where benefits-in-kind, such as services or staff time, are provided to an HCO by AZ or third parties, the monetary value of these benefits is disclosed against the HCO recipient.

Where benefits in kind are services in the form of donations (e.g., therapy review service) provided by third parties appointed by AZ to HCOs for the purpose of supporting healthcare or research, the value of the completed service provided to a specific HCO is tracked and recorded against the recipient HCO.

2.8 ToVs in case of partial attendances or cancellation and refund

Where an HCP/HCO does not receive the benefit due to a no show or cancellation of event, the associated costs are not reported, such as the cost of cancelling a hotel booking or accommodation. In case of partial attendance, only the benefits actually received are reported.

Where AZ has to pay cancellation fees to HCP/HCOs as per service contracts, due to cancellation of initiatives or events, these payments are reported.

2.9 Cross-border activities

AZ makes their best efforts to capture and report all ToVs to HCPs and HCOs with their primary practice in a country with EFPIA Disclosure Code and/or other cross border transparency reporting requirements and has introduced a group wide reporting requirement for that purpose.

The country of disclosure will be determined by the address of principal practice for HCPs and the address of registration for an HCO.

Disclosures are made locally, either on each affiliate's website, or on a separate disclosure platform if prescribed by the national code or law.

2.10 R&D

In accordance with the CGR Code, the remuneration of services and the sponsorship of research to which the Medical Research Involving Human Subjects Act (WMO) or the Standards Framework for Non-WMO-Regulated Research (i.e. non-interventional medical studies) applies, are exempt from the disclosure requirement.

In order to fulfill the EFPIA Code requirements, all transfers of value related to the planning or conduct of non-clinical studies, clinical trials and prospective non-interventional studies are reported on an aggregate basis on the AZ Netherlands website.

ToVs relating to retrospective non-interventional studies (even if these studies fall under the Standards Framework for Non-WMO-Regulated Research) are reported under the name of an individual HCP or HCO.

2.11 Voluntary disclosure

Not applicable

3 Specific considerations

3.1 Country unique identifier

The unique identifier used for disclosure purposes in the Netherlands is the BIG number for HCPs and KvK number for HCOs or POs.

3.2 Self-incorporated HCP

Where an HCP has set up their own company and they are the sole owner and AstraZeneca has made payments to that company for Services provided by the HCP, the ToVs have been disclosed against that individual HCP.

3.3 Multi-year agreements

- For agreements that extend over multiple years, AstraZeneca applies a split payment approach and the ToV is disclosed for the calendar year in which the payment or reimbursement is processed in our financial systems.
- Where ToVs relate to multi-year contracts, only the ToVs made in the reporting year are included. Where the ToV is a benefit in kind, values are reported on the date the recipient received the benefit.

3.4 Country specificities

The Netherlands follow the Code of Conduct for Pharmaceutical Advertising (CGR). EFPIA methodology and disclosures should be aligned with the CGR Code and transparency requirements for ToVs reported in the Netherlands.

3.5 Quality checks

AZ aims to ensure that the data included in the publicly available disclosure reports is complete to the best of our knowledge. AZ keeps its disclosure data under review and will amend and/or update its disclosure data if/when it becomes aware that its quality and accuracy could be improved.

Data sources and controls:

- Sources: Finance and procurement records, event management systems, grant/sponsorship tools, CRO/vendor invoices, and contracts.
- Controls: Recipient validation, category mapping review, reconciliation to POs/contracts, duplicate checks, and documented FMV estimations.
- AZ relies on a combination of automated systems, standardized processes, and manual data collection from internal and external resources to record and report relevant ToV data. The information reported is done in good faith and best efforts to comply with the requirements of the EFPIA Disclosure Code.

4 Data protection legal basis

4.1 Consent collection

Not applicable

4.2 Legitimate interests

The basis for mandatory ToV disclosure in the Netherlands is the CGR Code. In accordance with the Code, HCOs and HCPs practising in the Netherlands are not allowed to opt out of disclosure.

5 Form of disclosure

5.1 Date of publication

The date of publication for the Netherlands is mid-July, in line with the CGR Code of Conduct.

5.2 Data retention

AZ maintains the relevant records of the disclosures for a minimum of five years. The information disclosed is required to remain in the public domain for a minimum of three years after the time such information is first disclosed in accordance with Section 23.04. of the EFPIA Code of Practice.

5.3 Disclosure platform

Disclosure is made online via the local Transparantieregister Zorg portal: https://www.transparantieregister.nl/.

5.4 Disclosure language

Disclosure is made in Dutch language.

6 Disclosure financial data

6.1 Currency

Disclosure is made in euros. In the case of service provision by a healthcare professional, only the fee (excluding VAT and expenses) is to be registered. In case of sponsorship agreements, the full sponsorship amount is to be submitted. For in scope transactions requiring conversion, the calculation will be applied when the transaction is moved to the reporting environment, using the AZ Uniform Reference Environment (AZURE) rates. AZURE is what AZ utilizes for conversion rates for each currency.

6.2 VAT included or excluded

VAT is excluded for Service Fees, but is it included for Expenses related to Fees. VAT is also included for Sponsorships and Grants, unless the recipient organization is exempt from VAT.

6.3 Calculation rules

If a refund (full or partial) was issued for a ToV that had already been published in past disclosure reports which are still available, AZ will amend the relevant past disclosure report to deduct the refunded ToV amount.

It is not possible to publish negative amounts in the Netherlands disclosure report, therefore AZ reconciles the refund within the reporting year when the original ToV was made.

7 Additional Information

7.1 Pre-disclosure

A process allows HCPs and HCOs to review ToVs planned to be published prior to disclosure on the Transparantieregister Zorg website.

7.2 Management of recipient's requests

Requests or disputes are managed at a local level. HCPs or HCOs should contact AstraZeneca BV or their local day-to-day contact if they believe any data reported is inaccurate.

AstraZeneca commits to resolving disputes and republishing if required within 30 days of receiving notification of the dispute.