

Methodological Note for HCP/HCO Disclosure Data Year 2025

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Introduction

Collaborative working between medical professionals and healthcare organisations has long been a positive driver for advancements in patient care and the development of innovative medicine. Medical professionals and the organisations 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 invaluable 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 organisations should be fairly compensated for the services they provide to pharmaceutical companies. The EFPIA Code of Practice 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 Farmindustria and as a full corporate member of EFPIA, AstraZeneca (“AZ”) is committed to transparency around interactions with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), and that these are captured and reported in line with all applicable local transparency requirements.

AZ’s own policies are fully aligned with the aims of the EFPIA Code of Practice and its local interpretation in the Farmindustria Code of Conduct – to promote ethical and transparent interactions with the Healthcare community. Our Interactions with HCPs/HCOs are governed by the AZ Code of Ethics and supporting Global Standards which require that we run every part of our business with integrity and refuse to give or receive anything of value that may be 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 Code of Practice 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 that is 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

The entity included in reporting for Italy is: AstraZeneca S.p.A.

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1. Definitions

1.1. Recipients

1.1.1. Definition of an Healthcare Professional (HCP)

Any person who carries out their activity in the medical sector, dentistry, public, private or hospital pharmacies, any nurses, Administrators or staff of Local Health Authorities, any technical or administrative personnel of public or private healthcare structures and any other person within the scope of their professional activity can prescribe, dispense, purchase or administer a medicinal specialty and that has their activity mainly in Europe. Intermediary pharmaceutical distributors are however excluded.

Publication is determined by the recipient's status when the transfer of value was made, regardless of the later HCP status changes (retirement, job changes or passing away). Any ToV made within the calendar year must be included in the disclosure report for that year based on the consent provided in the contract.

1.1.2. Definition of an Healthcare Organization (HCO)

Any healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a Professional Congress Organisation (PCO), hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or through which one or more healthcare professionals provide services. For the application of this guidance, commercial companies involved in organisation of travel (travel agencies) or accommodation (hotels, banqueting functions in hotels, etc.) are not considered HCOs.

1.1.3. Definition of a Patient Organization (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 for medical or scientific education, advances in medical or scientific research, health or healthcare systems or disaster relief through financial or non-financial ToVs to legitimate, established organisations.

AZ can provide this support through:

- Contributions or Sponsorships (or referred to as Grants) to support initiatives in HCP Education, including education about healthcare systems and practices, Medical or Scientific Research, or Partnerships.
- Donations to a non-profit or public sector healthcare organisation (HCO) intended to support their charitable mission and activities. Donations and Grants to Patient Organisations (POs) or as part of Community Investments to charities and other non-profit non-HCOs are disclosed separately on www.astrazeneca.it

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 Agreements

AZ gives contributions, through financial or non-financial support to legitimate, established organisations 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.

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 (max two per year in conformity with the Farindustria code of conduct):

- 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 for services.

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

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 Organised 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 (for example bus or taxi) that are incurred 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 for services when there is a genuine and legitimate business need and where the HCP/HCO is qualified and appropriate to provide the services. These services are paid with a Fee for Service at Fair Market Value.

Under the relevant formalised contract governing the above services, it is provided that related expenses may be incurred and may include the costs of air travel, rail travel, car hire, tolls, parking, taxis, coach transfers, hotel accommodation and visas. All costs may be incurred directly by AZ or reimbursed upon presentation of appropriate receipts

These services can include:

- Speaking at and chairing meetings
- Training services
- Participation at 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 and any visa 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 (R&D)

For the purposes of disclosure, ToV for Research and Development means, transfers of value to health professionals or healthcare organisations related to the planning or conduct of:

- non-clinical studies (as defined in the OECD Principles of Good Laboratory Practice)
- clinical trials (as defined in EU Regulation 536/2014)
- non-interventional studies performed by AZ or by Clinical Research Organisations on AZ's behalf that are prospective in nature and that involve the collection of patient data from or on behalf of individual or groups of health professionals specifically for the study are considered Research & Development ToVs and are reported on an aggregate basis.

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. The ToVs related to those studies will be reported as Fee for Service under name of the individual recipient.

2. Scope of disclosure

2.1. Products concerned

AZ is a science focused company, developing innovative medicines that are prescription only medicines and interactions with HCPs/HCOs 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 that are provided by AstraZeneca Italy S.p.A., its affiliates and acquired or merged companies (if not disclosed under the acquired company name in a separate report) irrespective of their location, to HCPs or HCOs who practice or are registered in Italy.

2.3. Excluded ToVs

2.3.1. Hospitality costs

In accordance with Article 1.02 of the Code of Conduct on Transparency, hospitality costs (defined exclusively as costs relating to food and drink) do not need to be disclosed if they comply with the limits set by the national association, in accordance with Article 10 of the HCP Code. AZ applies these limits to meetings organised and sponsored by itself and, therefore, the costs of meals and drinks are excluded. However, in cases where meals and drinks form an integral and indivisible part of the sponsorship within the context of events organised by HCOs, these costs are included in the contributions towards the costs of the events.

2.3.2. Informational and educational materials and items of medical utility

As per Art 17 of the EFPIA Code of Practice, items of medical utility for HCPs and informational and educational material are not disclosed where "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."

2.3.3. Logistical costs

Logistical costs related to AZ Organised Meetings (for example 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.

2.3.4. Donations to charitable organisations & patient organisations

All ToVs to non-HCO organisations are out of scope and excluded for example charitable organisations.

Transfers of value to patient organisations are not disclosed, as there are separate reporting requirements regarding transparency of transfers of value to these organisations. These requirements are set out in the Farmindustria Code of Ethics governing relations between pharmaceutical companies and patient organisations

2.3.5. Continuing Medical Education (CME) regulation

Due to the provision of the applicable CME regulation, ToVs for CME events are not published, even in aggregate.

2.4. ToVs date

Where the ToV is a payment, values are reported on the date of the payment. Payments made in 2025 for activities related to 2024 are included. If consent to disclose these has been obtained, they are reported against the individual. If not, they will be reported in aggregate.

Where ToVs relate to multi-year contracts, only the ToVs made in the 2025 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 the AZ transparency reporting system. They are then mapped to the appropriate EFPIA disclosure activity category for reporting.

2.6. Indirect ToVs

2.6.1. Indirect ToVs through third parties for R&D activities

Where a third-party providing services for R&D activities acts on behalf of AZ to make ToVs to HCPs/HCOs, these are within scope 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 PCOs

Contributions provided to Events through PCOs, that would therefore be the Recipient of the ToVs, must be considered as indirect ToVs. ToVs through PCOs are reported either in the name of benefitting HCO, or in the name of Recipient PCO if the HCO is unknown. This applies whether PCOs organise Events on their own initiative, or at the request of an HCO.

Contribution to costs related to Events paid through PCOs to the benefit of individual HCPs must be reported on an individually named basis, as Indirect ToVs to HCPs, or in the name of Recipient PCO if the HCP is unknown. Disclosures on an individual name's basis are subject to appropriate consent; where such consent cannot be secured, related ToVs will be disclosed in aggregate.

2.6.3. Indirect ToVs through HCOs

In the case of ToV transfers made indirectly to an individual HCP via an HCO, and where AZ is aware of the HCP's name and has obtained consent for the publication of the data, such transfers will be attributed to the HCP.

2.6.4. 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 organised 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.

Where ToVs are made indirectly to an individual HCP for speaker and meeting chair services, and where AZ has obtained the consent, these will be disclosed against the HCP.

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

2.7. Non-monetary ToVs

Where benefits-in-kind, such as services or labor, 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 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

Where an HCP/HCO does not receive the benefit due to a no show or a 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 Code of Practice and/or other cross border transparency reporting requirements. 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

ToVs related to the planning or conduct of prospective non-clinical studies, clinical trials and non-interventional studies performed by AZ or by Clinical Research Organisations on AZ's behalf are considered Research & Development ToVs and are reported on an aggregate basis.

ToVs related to the planning or conduct of retrospective non-interventional studies or other studies that are not submitted to authorities as per local drug law performed by AZ or by Clinical Research Organisations on AZ's behalf, do not fall under the category of R&D activities. The ToVs related to those studies will be reported as Fee for Service under name of the recipient.

In addition to the activities stated above performed by AZ, or by Clinical Research Organisations on AZ's behalf, Research and Development includes ToVs related to Externally Sponsored Scientific Research (ESR). ESR is owned, conducted, and managed by a non-Company Sponsor*. ESR can be clinical or non-clinical in nature.

*NOTE: In this context Sponsor refers the party assuming the legal and/or regulatory accountability for the research, and takes responsibility for the initiation, management, and arrangements to finance a clinical trial as per the ICH E6 (R3) Guideline for good clinical practice (GCP).

2.11. Voluntary disclosure

Voluntary disclosure is not applicable.

3. Specific considerations

3.1. Country unique identifier

AZ provides one unique identifier for any HCP or HCO that is to be reported. This ID is generated by AZ and is used to ensure that transactions are reported against the correct recipient to facilitate collection of ToVs throughout Europe and across other affiliates.

3.2. Self-incorporated HCP

Where a HCP practices through a legal entity comprising solely the HCP, that entity is regarded as an HCO in its capacity as a legal person.

If an HCP is "self-employed" but has not set up a legal entity, they are treated as an 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 payment or reimbursement is processed in our financial systems.

3.4. Country Specificities

Until the formal, national implementation of Italian Sunshine Act, Italy follows the national pharmaceutical industry association Farmindustria Code of Ethics requirements. EFPIA methodology and disclosures should be aligned with Farmindustria's Code of Conduct and transparency requirements for transfers of value reported in Italy.

3.5. Quality Checks

AstraZeneca aims to ensure that the data included in the publicly available disclosure reports is complete to the best of our knowledge. AstraZeneca 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.

AstraZeneca 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 Farmindustria and EFPIA Disclosure Code.

4. Data protection legal basis

4.1. Consent collection

4.1.1. HCO consent

In Italy HCOs are reported without the need for a consent as they are legal entities.

4.1.2. HCP consent

All efforts have been made at local level to achieve a high level of individual HCP payment disclosure whilst recognising applicable Data Privacy regulations.

Consent is requested from HCP in the first contract for all future commitments. The HCP can revoke the consent at any given time.

HCPs' data are reported only after consent is given. If no response is received, a “no” response is assumed and the data are reported in aggregate.

4.1.3. Management of recipient consent withdrawal

Consent to disclose can be withdrawn at any time before and after public disclosure.

- If consent is withdrawn before disclosure the consent value is changed to "No"
- If consent is withdrawn after public disclosure, the published data is set off line and a revised report is uploaded that no longer shows the individual HCP ToV line but has integrated those ToVs in the aggregate line.

4.1.4. Partial consent

If consent is requested per engagement and the HCP provides partial consent, the final response (yes or no) will be applied to all transactions for that reporting year.

4.2. **Legitimate interests**

. Legitimate Interest is not applied in Italy.

5. Form of Disclosure

5.1. **Date of publication**

The date of publication for Italy is 30 June 2026 in line with EFPIA requirements.

5.2. **Data retention**

AZ maintains relevant records of the disclosures for a minimum of 5 years and the respective reports are kept available on AZ Sustainability site for 3 years as required in point 5.3 of Farindustria Code.

5.3. **Disclosure platform**

For Italy, disclosure is made on www.astrazeneca.it. Disclosure is also made on AstraZeneca's external website under the Sustainability section at www.astrazeneca.com. Disclosure of Patient Organisation (PO) transfers of value can be located on both the AstraZeneca website <https://www.astrazeneca.it/pazientieassociazioni.html>

5.4. Disclosure language

Disclosure is made in Italian.

5.5. Pre-disclosure

A process allows HCPs, who had given consent to disclose and for whom a valid e-mail address is present in AstraZeneca systems, to review ToVs planned to be published prior to disclosure on the AZ website

6. Disclosure financial data

6.1. Currency

Disclosure will be made in Euro. 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. Value added tax (VAT) and other taxes

VAT is excluded. Withholding tax is included.

6.3. Calculation Rules

Payments from HCPs or HCOs to AstraZeneca (e.g. due to corrections of incorrect payments or repayments due to cancellations) are published as negative payments or deducted from the total amount.

7. Additional Information