Astra Zeneca AB: Methodological Note for disclosure of transfer of Value (ToV) to HCP/HCO 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 EPFIA 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 Läkemedelsindustriföreningen (LIF) and the European Federation of Pharmaceutical Industries and Associations (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 Läkemedelsbranchens etiska regelverk, LER – 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 Sweden is AstraZeneca AB.

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1 Definitions

1.1 Recipients

1.1.1 Definition of an HCP

The definition of an HCP in Sweden is a physician, dentist, pharmacist, nurse or other who has the right to prescribe, purchase, supply, recommend or administer medicines, including employees of pharmaceutical companies whose main occupation is in the health care industry. Other employees of pharmaceutical companies or distributors are not included.

Treatment of retired and deceased: Transfers of Value to individuals who retire after receipt of value will be disclosed in the reporting year consistent with EFPIA categories. In the event of a recipient's death, report includes prior ToVs for the relevant year; future publication at individual level will cease.

1.1.2 Definition of an HCO

The definition of an HCO in Sweden is:

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 organisation (PO)

A definition of s PO in Sweden is:

Interest organisations such as disability organisations, patient associations, relatives' associations and other patient networks/associations. Also included are other interest organisations which form opinion within the healthcare sector, such as pensioners' organisations, the 1.6 Million Club, the Swedish Cancer Society, the Swedish Heart-Lung Foundation etc.

1.2 Kind of ToVs

1.2.1 Donations and Grants

AZ provides support to advances in medical or scientific research, through financial or non-financial ToVs to legitimate, established organisations.AZ can provide this support through donations or Grants to Medical or Scientific Research.

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 sponsorship is based on an approved budget for the education/scientific event. The mandatory Sponsorship Agreements will describe the purpose of the sponsorship.

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

Registration Fees are not provided to delegate HCPs, therefore this column does not apply.

1.2.4 Travel and Accommodation

Travel and accommodation are not provided to delegate HCPs, therefore this column does not apply.

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.

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

Research and development transfers of value' means, for the purposes of disclosure, 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 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.

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

Member Companies
Collectively, "corporate members" (as defined in the Code of Practice) of EFPIA, their respective parent companies, if different, subsidiary companies (irrespective of whether a subsidiary is a company or such other form of enterprise or organisation) and any companies affiliated with corporate members or their subsidiaries if such affiliated companies have agreed to be bound by this Code of Practice.

2.3 Excluded ToVs

2.3.1 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."

2.3.2 Donations to charitable organisations and POs

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

All ToVs to POs are in scope as required in the EFPIA Code of Practice and are reported separately on Sweden’s local trade association website.

2.3.3 Hospitality costs

As per Art 10 of the EFPIA Code of Practice, hospitality costs are not disclosable if in line with the limits set within the national association. AZ applies these limits for AZ Organised & Sponsored Meetings, and therefore costs of meals & drinks are excluded. However, where meals and drinks make up an integral and inseparable part of contributions to the cost of events or sponsoring as part of Sponsorship Agreements with HCOs, they have been included in Contributions to Cost of Events.

2.3.4 Logistical costs

Logistical costs related to AZ Organised Meetings (e.g. room hire, technics, personnel) are excluded. However, ToVs for speaker fee and related costs for their services such as travel and/or accommodation 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. Payments made in 2025 for activities related to 2024 are included.

Where ToVs relate to multi-year contracts, only the ToVs made in the reporting year are included.

2.5 Direct ToVs

Where the ToV is a benefit in kind, values are reported on the date the recipient received the benefit as available in AZ evidence.

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 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

Contribution to the costs related to consultancy engagements paid through PCOs to the benefit of individual HCPs/HCOs are reported on an individually named basis.

2.6.3 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.

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 (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 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, HCO, or PO 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 self-employed HCP is incorporated in a legal entity that consists of only that one HCP, this is considered as an HCO.

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.

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

Sweden follows the national pharmaceutical industry association LIF - Läkemedelsindustriföreningen. EFPIA methodology and disclosures should be aligned with LIF's Code of Conduct and transparency requirements for transfers of value reported in Sweden.

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.

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.

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 EFPIA Disclosure Code.

4 Data protection legal basis

4.1 Consent collection

4.1.1 HCO and PO consent

In Sweden HCOs and PCOs, are reported without the need for a consent as they are legal entities.

4.1.2 HCP consent

A clause is included in every engagement contract to provide HCPs notice that AZ uses the legitimate interest as the basis for individual disclosure.

4.2 Legitimate interests

AZ Sweden applies legitimate interest as the principal ground for disclosing individual transfers of value.

5 Form of disclosure

5.1 Date of publication

The EFPIA Disclosure report is published according to the timelines in the country defined by the industry association.

5.2 Disclosure platform

Disclosure is made on the Member Company's website.

For Sweden, disclosure is made at www.astrazeneca.com; under the section for "Hållbar verksamhet"/"Vårt sätt att arbeta" with a link from LIF's samarbetsdatabas.

Disclosure of PO transfers of value are reported into a public database on LIFs webpage: https://www.lif.se/etik/samarbetsdatabaser/

5.3 Disclosure language

Reporting is done in Swedish and English.

6 Disclosure financial data

6.1 Currency

Disclosure will be made in SEK. 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 and withholding taxes are 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

7.1 Management of recipient's requests

Requests or disputes are managed in concertation with AZ global or other AZ marketing companies, if applicable. AZ will follow minimum standard responses from corporate and commits to resolving and republishing if required within 30 days of receiving notification of the request or complaint.

7.2 Retention of data

AZ maintains relevant records of the disclosures for a minimum of 5 years.