

**Reporting of Transfers of Value to HCPs and HCOs
Methodological Note for Reporting of 2015 Data in 2016**



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1. Introduction

Approach to disclosure at AZ

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 Disclosure 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 Läkemedelsindustriföreningen, LIF, 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.

The aims of the EFPIA Disclosure Code and its local interpretation in the Läkemedelsbranchens etiska regelverk, LER – 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 Ethical Interactions (EI) Policy and supporting 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

The entity included in reporting for Sweden is: AstraZeneca AB

For Sweden, disclosure is made at www.astrazeneca.se with a link from LIF's samarbetsdatabas.

2. Definitions

2.1. Recipients

2.1.1. Definition of an HCP and what is reported on HCP

The definition of an HCP in Sweden is:

Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product, including employees of pharmaceutical companies whose main activity is with a Healthcare Organisation. Other employees of pharmaceutical companies or distributors are not included.

Fee for service paid to an individual and expenses related to the provided service, such as travel and accommodation, is reported on HCP

2.1.2. Definition of an HCO and what is reported on HCO

The definition of an HCO in Sweden is:

Any legal person (i) that is offering healthcare or conducting research or education within this area, or is a learned society with medical or scientific focus, with the exception for interest groups not included in chapter 3 of LER.

Fee for service and related expenses invoiced from companies is reported on HCO. For services provided by an HCP on behalf of a clinic/organisation, ToV is reported on HCO. Donations and grants are also reported on HCO.

2.1.3. What is reported on Other

For ToV to an HCP or a self-incorporated HCP, a consent for publication is needed in line with data privacy legislation. In case no consent has been provided, ToV is reported on an aggregate level. The number of recipients included in this aggregate amount and the percentage of the total number of recipients are also reported here.

2.2. Kind of ToVs

2.2.1. 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,

2.2.2. 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.

2.2.3. 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.

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

3. Scope of disclosure

3.1. What is included in the report

ToV to HCPs and HCOs related to activities linked to AstraZeneca's prescription medicines and over-the-counter medicines.

AstraZeneca is a science driven company that develops innovative prescription medicine. Our interactions with HCP/HCO are therefore focused on development and promotion of prescription medicines.

3.2. Excluded ToVs

3.2.1. Hospitality costs

As per Section 1.02 of the Disclosure Code, hospitality costs are not disclosable if in line with the limits set within the national association following Art 10 of the HCP Code. 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.

3.2.2. 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."

3.2.3. Logistical costs

Logistical costs related to AZ Organised Meetings (e.g. room hire, technicians, 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.

3.2.4. ToVs to charitable organisations & Patient Organisations

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

All ToVs to Patient Organisations are out of scope as separate reporting requirements provide transparency on ToVs to these organisations. These requirements are outlined in the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.

3.3. Date of ToVs

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 2015 for activities related to 2014 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 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. 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 EFPIA disclosure activity category 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).

3.5. Indirect ToVs

3.5.1. Indirect ToVs through CROs

Where a Clinical Research Organisation 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.

3.5.2. 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 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, 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.

3.6. 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.

3.7. Cross-border activities

3.7.1. 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.

4. Specific considerations

4.1. 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 and to automate and facilitate collection of ToVs throughout Europe and across other affiliates.

4.2. Self-incorporated HCP

Where a self-employed HCP is incorporated in a legal entity that consists of only that 1 HCP, this is considered as an HCO, as it is a legal entity but remains subject to providing consent, as per data privacy recommendations.

If an HCP is "self-employed" but has not set up a legal entity, they are treated as an individual HCP.

5. Consent management

5.1. Consent collection

5.1.1. HCO consent

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

5.1.2. 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 the HCP once, in the first contract valid for all future engagements in the year for the period the consent is given.

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.

Disclosure of personal data is based on written consolidated consent collected by AstraZeneca. Since the General Data Protection Regulation (GDPR) is more far-reaching than PUL, the consent collected prior to the publication of 2015 transfers to healthcare professionals is no longer valid. The report template for 2015 value transfers has therefore been aggregated / anonymized (May 2018).

5.2. Management of recipient consent withdrawal

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

- If consent is withdrawn before disclosure the consent value is changed to "No"
- Consent cannot be withdrawn following public disclosure. Data should be publicly available for three years and should not be changed unless the data is erroneous.

5.3. Management of recipient's requests

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

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

6. Disclosure form

6.1. Disclosure platform

6.1.1. Date of publication

The date of publication for Sweden is 31st of May in line with LIF decision.

6.1.2. Retention of data

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

6.2. Disclosure language

Disclosure is made in Swedish and English.

6.3. Pre-disclosure

A process allows HCPs to review ToVs planned to be published prior to disclosure on the AZ website.

7. Disclosure financial data

7.1. 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.

7.2. Value Added Tax (VAT) and other taxes

VAT is excluded and withholding taxes are included.