Reporting of Transfers of Value to HCPs, HCOs and POs
Methodological Note for Reporting of 2022 Data in 2023

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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 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 The Association of Pharmaceutical Manufacturers in Estonia (APME) and as a full corporate member of EFPIA, AstraZeneca ("AZ") is committed to transparency around interactions with Healthcare Professionals (HCPs), Healthcare Organisations (HCOs), and Patient Organisations (POs), 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 APME Ethical Code – to promote ethical and transparent interactions with the Healthcare community. Our interactions with HCPs/HCOs/POs 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 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 entities included in reporting for Estonia are:
AstraZeneca Eesti OÜ

Disclosure is made on AstraZeneca's external website under the Sustainability section at https://www.astrazeneca.com/sustainability/ethics-and-transparency/astrazeneca-and-global-transparency.html.
The purpose of publication is to comply with the transparency requirements of the EFPIA Code of practice, and it is not permitted to use published data for any other purposes.

2. Definitions

2.1. Recipients

2.1.1. Definition of an HCP

The definition of an HCP in Estonia 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 and whose primary practice, principal professional address or place of incorporation is in Europe.

2.1.2. Definition of an HCO

The definition of an HCO in Estonia 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.

2.1.3. Definition of a PO

The definition of a PO in Estonia is:

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.

2.2. Kind of ToVs

2.2.1. 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) or Patient Organisation (PO) intended to support their charitable mission and activities.

Donations to HCOs or POs 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.

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 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, the hiring of exhibition space 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 Agreements".

2.2.3. 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):

- 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.

2.2.4. 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 organised 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.

2.2.5. 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 at advisory board meetings
- Medical writing, including translation service
- 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.

2.2.6. 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 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. 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.

3.2. Excluded ToVs

3.2.1. 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

3.2.2. 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."

3.2.3. 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.

3.2.4. Donations to charitable organisations & patient organisations

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

All ToVs to Patient Organisations are in scope for reporting as outlined in the EFPIA Code of Practice.

3.3. Date of ToVs

Where the ToV is a payment, values are reported on the date of the payment. Payments made in 2022 for activities related to 2021 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.

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 the AZ transparency reporting system. They are then mapped to the appropriate EFPIA disclosure activity category for reporting.

3.5. Indirect ToVs

3.5.1. Indirect ToVs through CROs and other third parties for R&D activities

Where a Clinical Research Organisation or 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).

3.5.2. Indirect ToVs through PCOs

Contributions for the costs related to events paid through PCOs to the benefit of individual HCOs/HCPs must be reported on an individually named basis or in the name of recipient PCO if the HCOs/HCPs are unknown. Disclosures on an individual name basis will be reported on the basis of legitimate interest, unless HCP has explicitly opted out of the individual disclosure.

3.5.3. Indirect ToVs through HCOs

Where ToVs are made to an individual HCP indirectly via an HCO, must be reported on an individually named basis. Disclosures on an individual basis will be reported on the basis of the legitimate interest, unless HCP has explicitly opted out of the individual disclosure.

3.5.4. 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.

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, HCOs, and POs 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 AZ 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, 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 and to 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 one HCP, this is considered as an HCO, as it is a legal entity.

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 and PO consent

In Estonia HCOs and POs 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. AZ has concluded that legitimate interest, with the right to object, is the most appropriate ground for disclosing individual transfers of value. A privacy notice is included to every engagement contract to provide HCPs awareness of AZs position to take the legitimate interest as the basis for individual disclosure.

5.2. Management of recipient consent withdrawal

Global Payment Transparency conducts a data preview with HCPs whereby they can they change their position if they want. The process is detailed below. Where HCPs exercise their right under the Data Protection Act or under the General Data Protection Regulation (GDPR) to object to individual disclosure, those ToVs are reported in aggregate.

As part of AstraZeneca’s pre-disclosure process, HCPs have an opportunity to verify and/or object to individual disclosure via the AstraZeneca Pre-Disclosure Portal. Therefore, if an HCP objects, payment details will subsequently be included in the aggregate spend.

5.3. Management of recipient's requests

Requests or disputes are managed in concertation with AZ global or other AZ marketing companies, if applicable. A central email address for requests is dedicated to HCPs/HCOs communication. AZ will follow minimum standard responses from corporate and commits to resolving 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 Estonia is 1st of June in line with APME Ethical Code.

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 Estonian.

6.3. Pre-disclosure

AstraZeneca will determine if and the extent to which HCPs may review the ToVs that will be published prior to disclosure.

7. Disclosure financial data

7.1. Currency

Disclosure will be made in Euros. 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.