Reporting of Transfers of Value to HCPs, HCOs and POs
Methodological Note for Reporting of 2023 Data in 2024

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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 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 **Association of International Research-based Pharmaceutical Manufacturers** (SIFFA) 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 CODE OF PRACTICE (Latvia) - valid since December 1, 2020 – 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 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 entities included in reporting for Latvia are:
AstraZeneca Latvia Ltd

Latvia's HCP and HCO disclosure can be located at the Health Inspectorate of Ministry of Health website, https://www.vi.gov.lv/lv/pazinojums-par-biedribam-nodibinajumiem-un-arstniecibas-iestadem-sniegto-materialo-vai-cita-veida-atbalstu-0

Disclosure of R&D and Patient Organisation (PO) transfers of value can be located at AstraZeneca's external website under the Sustainability section on www.astrazeneca.com.

2. Definitions

2.1. Recipients

2.1.1. Definition of an HCP

The definition of an HCP in Latvia is:

Any natural person that is a representative of the medical, dental, pharmacy or nursing profession or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply or dispense a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or dispense medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

2.1.2. Definition of an HCO

The definition of an HCO in Latvia 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 Latvia 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 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
- 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.

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.

2.2.7. Hospitality Costs

Meals and drinks may be provided to healthcare professionals for the purposes of engaging in discussions to share product and disease related information with physicians and their staff. AstraZeneca will submit the value of any meals, drinks, and/or event venue costs related to an event. The value of meals provided is determined by dividing the total cost of the meal by the total number of participants of the meal. Participants may include physicians, mid-level practitioners' medical staff, and AstraZeneca representatives.

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. 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."

3.2.2. Donations to charitable organisations

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

3.3. Date of ToVs

Where the ToV is a payment, values are reported on the date of the payment. Payments made in 2023 for activities related to 2022 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 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 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).

3.5.2. Indirect ToVs through PCOs

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

3.5.3. Indirect ToVs through HCOs

Where ToVs are made to an individual HCP indirectly via an HCO and where AZ has obtained the consent, these will be disclosed against the HCP in line with local association guidelines.

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 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, 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.

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 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.

4.3. Remediation of data collection gap

We acknowledge that we have identified a gap in our data collection process for collecting transfers of values to HCPs due internal business process changes. The gap was identified in December 2023, the impact is small however, adequate measures were immediately undertaken to remediate the issue.
This includes ToVs which were not processed via any corporate platform integrated with financial systems (e.g., VEEVA, Cvent, etc.) and ToVs were delivered for services procured directly via BCD agency. These data elements will not be part of 2023 data sets, disclosed in 2024 reporting cycle.
According to the solution adopted – required data will be collected and disclosed for the period of 2024 in 2025 reporting cycle.

5. Consent management

5.1. Consent collection

5.1.1. HCO and PO consent

In Latvia, HCOs and POs are reported without the need for consent in accordance with Latvia's Cabinet Regulations No. 378

5.1.2. HCP consent

In Latvia, HCPs are reported without the need for consent in accordance with Latvia's Cabinet Regulations No. 378

6. Disclosure form

6.1. Disclosure platform

6.1.1. Date of publication

The date of publication for Latvia is 30 May in line with Latvia's local Code of Practice.

6.1.2. Retention of data

AZ maintains relevant records of the disclosures for a minimum of 5 years. The information disclosed shall be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed in accordance with Section 2.04 of the EFPIA Code of Practice, unless a shorter period is required under applicable data privacy or other laws or regulations of the Republic of Latvia.

6.2. Disclosure language

Disclosure is made in the local language or English.

6.3. Pre-disclosure

AZ 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 EUR in Latvia. 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.