

**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 organizations has long been a positive driver for advancements in patient care and the development of innovative medicine. Medical professionals and the organizations 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 organizations 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 Asociace Inovativního Farmaceutického Průmyslu and as a full corporate member of EFPIA, AstraZeneca (“AZ”) is committed to transparency around interactions with Healthcare Professionals (“HCPs”) and Healthcare Organizations (“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 AIFP CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS (“Disclosure Code”) – 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

In each country, AZ will comply with applicable local disclosure requirements implemented by local association.

(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 the Czech Republic is AstraZeneca Czech Republic s.r.o., based in Prague, Jinonice, U Trezorky 921/2, Id Nr. 63984482, registered in the Commercial Register maintained by the Municipal Court in Prague, file no. C 38108

For the Czech Republic, disclosure is made at www.transparentnispoluprace.cz.

2. Definitions

2.1. Recipients

2.1.1. Definition of an HCP

The definition of an HCP in the Czech Republic is:

Any natural person that may prescribe or dispense medicinal products and whose primary practice, principal professional address or place of incorporation is in Czech Republic.

2.1.2. Definition of an HCO

The definition of an HCO in the Czech Republic is:

Any legal person (i) that is a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in the Czech Republic or (ii) through which one or more HCPs provide services.

2.2. Kind of ToVs

2.2.1. Donations and Grants

AZ provides support to 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.

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.

2.2.2. Sponsorship agreements

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

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

- 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.

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

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 (e.g. bus or taxi) that are organized 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 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 agreement for services, 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.

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 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 Section 1.02 of the Transparency Code, hospitality costs are not disclosable. 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 Disclosure Code, items of medical utility for HCPs and informational and educational material are not disclosed where in line with the AIFP Code of Ethics.

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. Donations 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 relevant year for activities related to previous year 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 the ToV is a benefit in kind, values are reported on the date the recipient received the benefit.

3.4. Direct ToVs

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 Organization acts on behalf of AZ to make ToVs to HCPs/HCOs, these are within the scope of the Disclosure code 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 organized on behalf of multiple HCOs without clarity on allocation, the value is divided equally between the HCOs, unless the ToV is provided forthrightly to one of 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.

3.5.3. 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.

3.6. 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 each 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.

Self-employed HCPs with main practice in Czech Republic are treated as HCPs.

5. Consent management

5.1. Consent collection

5.1.1. HCO consent

In the Czech Republic 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 recognizing applicable Data Privacy regulations.

A consent clause is attached to every engagement contract. This allows continuous tracking of HCP's consent status and updating of the granted consent. Granted consent is considered valid until revocation is delivered to AZ by the HCP.

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.

5.2. 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" and data are not disclosed.
- Where disclosure on a national platform, after data is published on www.transparentnispoluprace.cz, consent withdrawal follows the external process defined.

5.3. Management of recipient's requests

Requests or disputes are managed at a local level. HCPs or HCOs should reach out to AZ via email address or phone or contact their day-to-day contact if they believe any data reported is inaccurate.

All requests and complaints will be resolved without any undue delay.

5.4. 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.

6. Disclosure form

6.1. Disclosure platform

6.1.1. Date of publication

The date of publication for the Czech Republic is 1 July of relevant year in line with the Disclosure Code.

6.1.2. Retention of data

Data remain published for a period of 3 preceding years.

6.2. Disclosure language

Disclosure is made in Czech and English language.

6.3. Pre-disclosure

A process allows HCPs to review ToVs planned to be published prior to disclosure on the website and apply and objections or comments to it.

7. Disclosure financial data

7.1. Currency

Disclosure will be made in Czech Crowns. For in scope transactions in other currencies the amounts will be converted to Czech Crowns.

7.2. Value Added Tax (VAT) and other taxes

Value Added Tax is excluded and all ToVs published are net of VAT.