

**Reporting of Transfers of Value to HCPs and HCOs
Methodological Note for Reporting of 2017 Data in 2018**



Contents

1. Introduction.....	4
Approach to disclosure at AZ.....	4
2. Definitions	5
2.1. Recipients	5
2.1.1. Definition of an HCP.....	5
2.1.2. Definition of an HCO	6
2.2. Kind of ToVs	6
2.2.1. Donations and Grants	6
2.2.2. Sponsorship agreements	6
2.2.3. Registration fees	7
2.2.4. Travel and Accommodation.....	7
2.2.5. Fees for service and consultancy and related expenses	8
2.2.6. Research and Development.....	8
3. Scope of disclosure	8
3.1. Products concerned	8
3.2. Excluded ToVs.....	9
3.2.1. Hospitality costs	9
3.2.2. Informational and Educational Materials and Items of Medical Utility ..	9
3.2.3. Logistical costs.....	9
3.2.4. Donations to charitable organisations & Patient Organisations	9
3.3. Date of ToVs	9
3.4. Direct ToVs	10
3.5. Indirect ToVs.....	10
3.5.1. Indirect ToVs through CROs	10
3.5.2. Indirect ToVs through other third parties	10
3.5.3. Indirect ToVs through HCOs	10
3.6. ToVs in case of partial attendances or cancellation.....	10
3.7. Cross-border activities	11
3.7.1. Cross-border activities	11
4. Specific considerations	11
4.1. Country unique identifier	11
4.2. Self-incorporated HCP	11
5. Consent management	12

5.1.	Consent collection.....	12
5.1.1.	HCO consent	12
5.1.2.	HCP consent.....	12
5.2.	Management of recipient's requests.....	12
6.	Disclosure form	12
6.1.	Disclosure platform	12
6.1.1.	Date of publication	13
6.1.2.	Retention of data.....	13
6.2.	Disclosure language.....	13
6.3.	Pre-disclosure	14
7.	Disclosure financial data.....	14
7.1.	Currency	14
7.2.	Value Added Tax (VAT) and other taxes	14

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 SFEE 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.

According to article 66 par. 7a of Law 4316/2014, pharmaceutical companies are obliged to publish at their websites as well as at the website of National Organization of Medicines, at a central or individual base, the provisions that they offer, in each case, to Healthcare Professionals (HCP) and HealthCare Organizations (HCOs).

According to Greek legislation, AstraZeneca is obliged to disclose payments and provisions to HCP and HCOs, such as donations, subsidies, contribution to events’ costs and payment for advisory and other services, centrally or individually, depending on each case, when this is mandatory. Respectively, AZ is obliged to share with the National Organization of Medicines data related with payments and provisions to Healthcare Professionals (HCP) and HealthCare Organizations, in order to be published also at the website of the National Organization of Medicines, when this is provided and ordered by the regulatory directive of National Organization of Medicines from 6-6-2018.

The aims of the EFPIA Disclosure Code and its local interpretation in the SFEE Code of Ethics – 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 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 Greece is:
AstraZeneca SA

For Greece, disclosure is made at the AstraZeneca site (<https://www.astrazeneca.com/country-sites/greece.html>) and the EOF (National Organisation for Medicines) site (www.eof.gr). Disclosure is also made on AstraZeneca’s external website under the Sustainability section at www.astrazeneca.com.

2. Definitions

2.1. Recipients

2.1.1. Definition of an HCP

The definition of an HCP in Greece is:

Any natural person that is a member 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 administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Greece. For the avoidance of doubt, the term “Healthcare Professional” includes: (i)

any official or employee of a government agency or other organisation (whether in the public or in the private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a SFEE Member Company whose primary occupation is that of a practicing HCP. This latter category excludes: (a) all private physicians having a lasting collaboration with a SFEE member company SFEE under an employment contract, an agency contract agreement or contract for work; and (b) all wholesalers or distributors of medicinal products.

2.1.2. Definition of an HCO

The definition of an HCO in Greece is:

Any legal person: (i) that is a healthcare, medical or scientific association (scientific society or an association of HCPs) or healthcare organisation (irrespective of the legal or organisational form), such as a hospital, clinic, foundation, university or other educational institution or learned society of any type (e.g. NGOs) sponsored by pharmaceutical companies (except for patient associations within the scope of the SFEE Code of Ethics on the Relationships between Pharmaceutical Companies and Patient Associations), which has registered office or is active in Greece; or (ii) through which one or more HCPs provide healthcare services, including private Primary Healthcare Providers (Presidential Decree 84/2001, Gov. Gazette 70/A/10.4.2001).

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) intended to support their charitable mission and activities. Donations and Grants to Patient Organisations or as part of Community Investments to charities and other non-profit non-HCOs are subject to separate disclosure and thus excluded.

Donations to HCOs can be both monetary and donations in kind. Product Donations subject to the applicable law 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 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, and hotel accommodation. All costs are paid by AZ to travel and or /accommodation providers or meeting organizers (where relevant).

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.

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 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 (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 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. Payments made in 2018 for activities related to 2017 2016 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 Third Parties for R&D Services

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 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.

3.5.3. Indirect ToVs through HCOs

Where ToVs are made to an individual HCP indirectly via an HCO, 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. 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 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.

5. Consent management

5.1. Consent collection

5.1.1. HCO consent

In Greece HCOs are reported without the need for a consent as the disclosure is mandatory as per article 66/paragraph 7a of law 4316/2014. Furthermore, HCOs are legal entities and therefore any information relating to them does not classify as personal data.

5.1.2. HCP consent

In Greece, the consent of the HCPs is not required, as the report and disclosure of payments by pharmaceutical companies to HCPs is mandatory pursuant to article 66 paragraph 7a of Law 4316/2014. Pursuant to the Opinions under No 5/2016 and No 2/2017 issued by the Hellenic Data Protection Authority (DPA), as well as the recent regulatory directive of National Organization for Medicines from 6-6-2018, it is provided that the obligation of the pharmaceutical companies regarding the abovementioned disclosure does not apply to payments performed via ELKE to university HCPs as well as to public HCPs, since such payments are already disclosed via the program DIAVGEIA.

However, according to the applicable data protection legal framework, HCPs have the right to access, objection, rectification, erasure, restriction of processing, as well as the right to data portability, pursuant to articles 16-21 of the General Data Protection Regulation 2016/679. Subjects can exercise their rights by post or email, as it is described at 5.2.

5.2. Management of recipient's requests

Requests or disputes are managed at a local level. HCPs or HCOs should email AZGRToVDisclosure@astrazenecae.com or call 210 6871690 if they believe any data reported is inaccurate. AZ commits to resolving disputes and republishing if required within 30 days of receiving notification of the dispute.

6. Disclosure form

6.1. Disclosure platform

Disclosure of provisions takes place at the website of the Company www.astrazeneca.gr. According to the applicable law, the Company will share with the National Organization for Medicines, the data disclosed as described, pursuant to its recent regulatory directive form 6-6-2018, as it is published at its website.

6.1.1. Date of publication

The date of publication for Greece, for 2017, is 29 June 2018 and will take place centrally or/and individually, depending on each case, and in line with EFPIA requirements. At National Organization for Medicines' website the publication will take place till 30-9-2018, pursuant to its regulatory directive form 6-6-2018.

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 the local language as per local requirements.

6.3. Pre-disclosure

A process allows HCPs and HCOs 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 Euro. 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 and withholding taxes are excluded.

The disclosure of provisions, either at a central or at an individual base, depending on the case, aims to the recording of the provisions (financial or in kind) to Healthcare Professionals/ Healthcare Organizations, that our company collaborates with, pursuant to article 66 par. 7a of Law 4316/2014, as well as to the goals and the terms included in the Code of Disclosure of SFEE. We explicitly mention that, this publication has been drafted after the issuance of the Opinions No 5/2016 and 2/20176 of the Hellenic Data Protection Authority (DPA) from 29-6-2016 and 13-4-2017 respectively, as well as after the issuance of the recent regulatory directive of the National Organization for Medicines and its context from 6-6-2018, that we have been aware of, and as it is published at its website. We reserve our right to an updated disclosure of the above described provisions, in case a most recent regulatory directive is issued. This disclosure does not authorize or enable any user of our website or of the National Organization for Medicines platform to further process the personal data of Healthcare Professionals.