

Reporting of Transfers of Value to Health Care Professionals (HCPs), Health Care Organisations (HCOs), and Patient Organisations (POs).

Methodological notice about publications in 2024 about the data regarding 2023

Data of Publication/Update: 23 June 2024



# **Contents**

1.	Introduction4			
	Approach	to disclosure at Alexion4		
2.	Definitions5			
	2.1. Recipients			
		5		
	2.1.1.	Definition of an HCP5		
	2.1.2.	Definition of an HCO		
	2.1.3.	Definition of an PO5		
	2.2 A non-profit organisation - including umbrella organisations to which they belong - composed primarily of patients and/or their caregivers that represents and/or supports the needs of patients and/ or their caregivers, , place of incorporation or primary place of operation is in Europe.Kind of ToVs			
	2.2.1.	Donations5		
	2.2.2.	Sponsorship Agreements 6		
	2.2.3.	Other sponsorship agreements: Partnership agreements		
	2.2.4.	Registration Fees		
	2.2.5.	Travel and Accommodation 7		
	2.2.6.	Fees for Service and Consultancy and Related Expenses		
	2.2.7.	Research and Development		
3.	Scope o	of disclosure8		
	3.1	Products concerned		
		8		
		Excluded ToVs		
		8		
	3.2.1.	Hospitality costs		
	3.2.2.	Informational and educational materials and items of medical utility . 8		
	3.2.3.	Logistical costs		
	3.2.4.	Donations to charitable organisations & Patient Organisations 9		
		Date of ToVs		
	3.4	Direct ToVs		



	3.5.1.	Indirect ToVs through third parties for R&D activities	9
	3.5.2.	Indirect ToVs through other third parties	10
	3.5.3.	Indirect ToVs through HCOs	10
		ToVs in case of partial attendances or	
		Cross-boro	
		Cross-border activities	
4.		ic considerations	
	•	Country uniq	
		Country uniq	
		Self-incor	
		Remediation of data co	• .
_		nt management	
J.		Conse	
		Consc	
	5.1.1.	HCO and PO consentError! Bookmark r	ot defined.
	5.1.2.	HCP consentError! Bookmark r	ot defined.
		Management of recipier	•
		Error! Bookmark	
6.		sure form	
		Disclos	•
	6.1.1.		
		Retention of data	11
	0.1.2.		
	6.3	Pr	e-disclosure
			11
7.		sure financial data	
			•
		Value Added Tax (VAT) and	



#### 1. Introduction

# Approach to disclosure at Alexion

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 Farmaindustria and as a full corporate member of EFPIA, Alexion 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.

Alexion's own policies are fully aligned with the aims of the EFPIA Code of Practice and its local interpretation in the "Code of Practice for the Pharmaceutical Industry" – to promote ethical and transparent interactions with the Healthcare community. Our interactions with HCPs/HCOs/POs are governed by the Alexion 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 Alexion 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 Alexion'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 Alexion 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, Alexion 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 Alexion or indirectly through third parties acting on behalf of Alexion

For Alexion Spain, disclosure is made on AstraZeneca's external website under the Sustainability / Ethics and transparency section at https://www.astrazeneca.com

### 2. Definitions

# 2.1. Recipients

# 2.1.1. Definition of an HCP

The definition of an HCP in Spain is:

Any member of the medical, dental, pharmaceutical, nursing or podiatric profession, any other person legally considered as such, or any other person who, in exercising their profession, may perform or participate in the prescription, purchase, supply, dispensation or administration of medicinal products for human use. For the purpose of this report veterinarians are excluded from this concept.

## 2.1.2. Definition of an HCO

The definition of an HCO in Spain is:

Any legal body or entity (i) that is a medical or scientific organisation, healthcare institution (of any legal status or organisation), such as hospitals, clinics, foundations, universities and other academic entities, scientific societies (excluding Patient Organisations), or (ii) through which one or more Healthcare Professionals provide services.

# 2.1.3. Definition of an PO

The definition of an PO in Spain is:

2.2. A non-profit organisation - including umbrella organisations to which they belong - composed primarily of patients and/or their caregivers that represents and/or supports the needs of patients and/ or their caregivers, , place of incorporation or primary place of operation is in Europe.Kind of ToVs

# 2.2.1. Donations

Financial contributions which Alexion makes to public non-profit organizations declared of public utility. These Donations are covered in Article 16 of Law 49/2002. Some examples are:



- Grants for scientists, healthcare or educational projects.
- Organization of congresses (not only intended to pay hospitality expenses).
- Support with Workshops and training courses (not only intended to pay hospitality expenses).

Donations are only given for a particular purpose, justifying the scientific reason, the occasion of the event etc., for which the donation is made.

Alexion Spain does not donate lasting medical equipment for use in the treatment or diagnosis and / or medical equipment such as spirometers, stethoscopes and thermometers. The donations are considered to be an exceptional form of collaboration with the HCO.

# 2.2.2. Sponsorship Agreements

Financial contributions (not only intended for payment of hospitality expenses) for an activity, initiative or projects under the following conditions:

- Alexion name is associated with the activity (for example, through the logo).
- Alexion can get opportunities to improve their reputation.

Typical cases:

- Research or training scholarships.
- Awards.
- Conferences, courses.
- Websites.
- Books, manuals.

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. Other sponsorship agreements: Partnership agreements

Financial contributions (not only intended for payment of hospitality expenses) to Foundations and non-profit organizations declared of public utility, covered in Article 16 of Law 49/2002 for an activity or project or initiative where the following conditions apply:

- The organization undertakes to disseminate by any means the Alexion's collaboration within the activity (for example through materials including logo in the activity).
- Alexion can receive opportunities to improve their reputation.

Typical cases include:

- Research or training scholarships.
- Awards.
- Conferences, courses.



# 2.2.4. Registration Fees

As part of support to continuous medical education, Alexion 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, Alexion 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 Alexion products or uses or related to Alexion'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.

# 2.2.5. Travel and Accommodation

As part of support to continuous medical education, Alexion provides support to HCOs or HCPs to cover the costs for Travel and Accommodation for HCPs to attend selected independent congresses and/or 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.

## 2.2.6. Fees for Service and Consultancy and Related Expenses

Alexion 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 Alexion 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 Alexion to travel and or /accommodation providers or meeting organizers (where relevant) or reimbursed supported by appropriate receipts.

# 2.2.7. Research and Development

All ToVs related to the planning or conduct of non-clinical studies, clinical trials and non-interventional studies performed by Alexion or by Clinical Research Organisations on Alexion's behalf that are prospective in nature are considered Research & Development ToVs and are reported on an aggregate basis.

## 3. Scope of disclosure

#### 3.1. Products concerned

Alexion 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. Alexion applies these limits for Alexion 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. <u>Informational and educational materials and items of medical utility</u>

As per Art 17 EFPIA Code of Practice for the Pharmaceutical Industry, 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 Alexion 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 asoutlined in the EFPIA Code of Practice and Farmaindustria Code.

#### 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. 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 of the payment to the third-parties, instead on the date the recipient receive the benefit in kind.

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

#### 3.5. Indirect ToVs

# 3.5.1. <u>Indirect ToVs through third parties for R&D activities</u>

Where a third party providing services for R&D activities acts on behalf of Alexion 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. <u>Indirect ToVs through other third parties</u>

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 Alexion 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 Alexion has obtained the consent, these will be disclosed against the HCP in line with local Farmaindustria 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 Alexion 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

Alexion 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

Alexion provides one unique identifier for any HCP,HCO, or PO that is to be reported. This ID is generated by Alexion and is used to ensure that transactions are reported



against the correct recipient to facilitate collection of ToVs throughout Europe and across other affiliates. It is included the NIF or CIF in an anonymize format.

# 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

Consent was not obtained for data collection year 2023. As such, to comply with data privacy regulations, Alexion will disclose individual HCP and HCO ToVs in their respective aggregate sections of the disclosure report.

#### 6. Disclosure form

### 6.1. Disclosure platform

### 6.1.1. Date of publication

The date of publication for Spain is before 30 June in line with Farmaindustria requirements.

# 6.1.2. Retention of data

Alexion maintains relevant records of the disclosures for a minimum of 3 years.

### 6.2. Disclosure language

Disclosure is made in Spanish.

## 6.3. Pre-disclosure

Alexion 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 Alexion Uniform Reference Environment (AZURE) rates. AZURE is what Alexion utilizes for conversion rates for each currency.

# 7.2. Value Added Tax (VAT) and other taxes

VAT is excluded. Withholding tax is included.