

# Methodological Note

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ADVANZ PHARMA is committed to ensuring transparency of relationships with healthcare professionals (HCPs), healthcare organisations (HCOs), patient organisations (POs), by operating within Farmaindustria (Asociación Nacional Empresarial de la Industria Farmacéutica), aligned with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on Disclosure on Transfers of Value.

Transfers of Value (ToV) i.e. payments or benefits received by HCPs, HCOs, POs during the 2023 calendar year will be disclosed on the ADVANZ PHARMA Ethics and Transparency page: <https://www.advanzpharma.com/ethics-and-transparency> and made public on 30<sup>th</sup> June 2023.

The principles applied in this methodological note are relevant to Spain only.

## Definitions

- “Healthcare Professional (HCP)”: A member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his/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 Spain.

If an HCP has set up a private company, as a sole director, they will be considered an HCP for disclosure purposes. Part-time employees or contractors of ADVANZ PHARMA (including employees or contractors of ADVANZ PHARMA’S appointed agencies and third-party vendors) who are not also an employee of an HCO would fall outside the scope of disclosure for ToVs made by ADVANZ PHARMA. For example, if an employee or contractor is providing full time services to ADVANZ PHARMA (or to ADVANZ PHARMA’S appointed agencies or third-party vendors) and they are not also employed by an HCO then this would not be considered as reportable.

HCPs who have worked with ADVANZ PHARMA may ask for their fee to be paid to charity. ADVANZ PHARMA does not encourage this type of fee payment and all payments are normally made directly to the HCP; where payment to a charity may occur the disclosure is still made against the individual HCP.

- “Healthcare Organisation (HCO)”: A healthcare, medical or scientific association or organisation (e.g., 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 Spain; or an organisation through which one or more HCPs provide services.
- “Patient organization (PO)”: An organisation mainly comprising of patients and/or caregivers or any user organisation such as a disability organisation, carer or relative organisation and consumer organisation that represents and/or supports the needs of patients and/or caregivers.
- “Research and Development (R&D)”: HCP/HCO transfers of value that relate to the planning and conduct of:
  - Non-clinical studies (as defined in OECD Principles on Good Laboratory Practice);
  - Clinical trials (as defined in Directive 2001/20/EC);
  - Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study. This also includes investigator sponsored research (ISRs).

## Disclosure Categories

In 2023 ADVANZ PHARMA has disclosed the following financial & non-financial payments:

	<b>Example activities</b>	<b>HCP</b>	<b>HCO</b>	<b>PO</b>
<b><u>Contracted Services</u></b> ToVs resulting from or related to a contract where the HCP / HCO/ PO provides services.	Advisory Boards Speaker Services Consulting Services Steering Committees Market Access / Market Research*	✓	✓	✓
<b><u>Related expenses to the contracted service</u></b> ToVs directly related to a fee for service contract**.	Travel (incl. flights, taxi, train, parking) Accommodation	✓		✓
<b><u>Sponsorship agreements</u></b> ToVs made to either the HCO/PO directly or to an event organizer or other third party appointed by the HCO/PO to manage an educational or scientific event.	Congress sponsorship Stand / booth sponsorship		✓	✓
<b><u>Support to attend third party led educational meetings</u></b>	Registration Fees	✓	✓	
	Travel & Accommodation	✓		
<b><u>Donations**</u></b> Non-financial support provided for an unspecified purpose.	Donations		✓	✓
<b><u>Grants**</u></b> Funding provided to support a specific activity that provides educational benefit or enhances patient care.	Grants		✓	✓
<b><u>Research and development</u></b> ToVs related to non-clinical studies, clinical studies and non-interventional studies.	Investigator site fees Advisory boards related to R&D Expert meeting services Data safety monitoring boards Steering Committee meetings Investigator sponsored research	✓	✓	
<b><u>Benefits in kind</u></b>	AVEP Provision of free passes to educational events	✓	✓	✓

\* Market access and market research costs where the identify of the individual is known to ADVANZ PHARMA, where these activities are “blind” or unknown to ADVANZ PHARMA, these disclosures are not made.

\*\* Donations and grants for medical educational projects. ADVANZ PHARMA’s funding policies in these circumstances require that ADVANZ PHARMA has no influence over the details of the project. As ADVANZ PHARMA would not influence or select HCPs involved in such projects, ADVANZ PHARMA would disclose such payments under an HCO category where such definition is met by the independent company. Where ADVANZ PHARMA is requested by an HCO to provide a financial grant to assist its employees to attend third party medical meetings, where possible the payment will be disclosed against a named individual HCP. Where ADVANZ PHARMA is not aware of the identity of recipient HCPs, the grant is declared against the named healthcare organisation.

The following categories were deemed out of scope for disclosure:

1. All costs associated with meetings run solely by ADVANZ PHARMA except for fees paid to individual HCPs providing services as speakers;

2. All costs associated related to OTC medicines and Medical Devices.
3. All costs associated to meals and subsistence
4. All delivery of samples
5. All articles of medical utility and educational or informative materials to HCPs

### **Data Privacy & Consent Methodology**

In the case of HCPs, in accordance with Article 7f) of Directive 95/46, on the protection of individuals with regard to the processing of personal data and the free movement of such data, there is a legitimate interest of the companies subject to the Code, recognized by the AEPD in its Report dated April 22, 2016, so that consent is not necessary for the publication on an individual basis of the Transfers of Value to HCPs. In any case, ADVANZ PHARMA shall inform HCPs, pursuant to Organic Law 3/2018 of December 5, 2018, on the Protection of Personal Data and Guarantee of Digital Rights, that their data will be published in accordance with the provisions of Farmaindustria Code of Practice.

In the case of HCOs, the Transfers of Value made by ADVANZ PHARMA to them is published on an individual basis.

To the extent legally possible and provided that it can be provided accurately and consistently, pharmaceutical companies should publish this information on an individual basis, identifying the Healthcare Professional (rather than the Healthcare Organization).

R&D & POs interactions are disclosed in aggregate for all transfers of values.

## **ToV Transaction Principles**

### **Payments to Third Party Organisations for Services Provided by Individual HCPs**

In some cases ADVANZ PHARMA contracts with HCPs through a third party agency. In such cases, ADVANZ PHARMA will disclose any payments made to the individual HCP by the service agency as if the payment had been made directly by ADVANZ PHARMA to that HCP.

### **VAT & Fees**

For all ToVs, VAT and other applicable taxes and business-related fees (e.g. administration fees) are excluded.

### **Transaction Date**

ToVs are reported based on payment date or transfer of value date (e.g. the date a flight was taken). Where an interaction with an HCP, HCO, or PO runs for more than one year, ADVANZ PHARMA will disclose ToVs made in the year of payment or transfer.

### **Transfer in foreign currencies**

ADVANZ PHARMA discloses ToVs in EUROS (€). Where ToVs are made in another currency, the invoice amount will be converted into EUROS (€) using a monthly exchange rate. Amounts disclosed may therefore vary slightly from the exact amounts paid.

### **Cross-Border Payments**

All disclosures are made in the country in which the HCP or HCO practice is located. Payments made to Spain-based HCPs or organisations by ADVANZ PHARMA overseas operations are disclosed within Spain.

### **Cancellations and non-participation**

ToVs will only be disclosed where the benefit has been received. In the event of a cancellation or where an HCP, HCO, or PO does not receive the benefit due to non-participation, ADVANZ PHARMA will not disclose ToVs against such HCP, HCO or PO.

### **Co-Marketing Projects**

Where ADVANZ PHARMA jointly markets a product with another pharmaceutical company, ADVANZ PHARMA will only declare those payments made directly from ADVANZ PHARMA bank accounts and listed in the company records as part of its normal business operations. Transfers of value made by its co-marketing partners will be disclosed separately by those organisations.

## **Disclosure Principles**

All Transfers of Value (ToV) i.e. payments or benefits received by HCPs/HCOs including research related spend are disclosed on a central platform managed by FARMAINDUSTRIA <https://www.codigofarmaindustria.org/servlet/sarfi/colaboracionesps.html> and made public on 30<sup>th</sup> June 2023.

All Transfers of Value (ToV) i.e. payments or benefits received by POs are disclosed on a central platform managed by FARMAINDUSTRIA <https://www.codigofarmaindustria.org/servlet/sarfi/colaboracionesop.html> and made public on 30<sup>th</sup> June 2023.

Additionally, Transfer of Value above are disclosed on the ADVANZ PHARMA Ethics and Transparency page: <https://www.advanzpharma.com/ethics-and-transparency> and made public on 30<sup>th</sup> June 2023.

The disclosure of transfers of value to a PO must include both the monetary value and a description of that support to enable the reader to understand the nature of that support or the arrangements.

ADVANZ PHARMA will maintain public disclosures for a minimum of three (3) years and will retain records for at least five (5) years after the end of the calendar year to which they relate.