

## DISCLOSURE OF TRANSFERS OF VALUE: SUMMARY OF METHODOLOGY

*Transfers of value disclosed for the year 2021 include those made by Audentes to the Spanish Healthcare Professionals in 2021. Audentes is a company that was integrated into Astellas Pharma in April 2021.*

### 1. ASTELLAS'S COMMITMENT

- 1.1 Astellas is a member company of the European Federation of Pharmaceutical Industries and Associations (“**EFPIA**”). The EFPIA Code (the “**EFPIA Code**”) requires all member companies to document and disclose certain Transfers of Value they make, directly or indirectly, to or for the benefit of, Healthcare Professional (“**HCPs**”) or Healthcare Organisations (“**HCOs**”) (“**Disclosures**”). The EFPIA Code is implemented in **Spain** by the Spanish Code of Good Practices for the Pharmaceutical Industry.
- 1.2 Astellas discloses all Transfers of Value to HCPs and HCOs in accordance with its commitment to the EFPIA Code and the Spanish Code of Good Practices for the Pharmaceutical Industry in Spain.
- 1.3 This note summarises the methodologies used by Astellas in preparing Disclosures in compliance with the EFPIA Code.

### 2. DEFINITIONS

- 2.1 The EFPIA Code defines the following terms:

- **Healthcare Organisation (HCO)**: any legal person/entity (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for POs within the scope of article 21) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.
- **Healthcare Professional (HCP)**: any natural person that is 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 Europe. For the purpose of this Code, the definition of HCPs 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, recommend or administer 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.
- **“Transfer of Value (ToV)”**: Direct and indirect ToV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of POM exclusively for human use. Direct ToVs are those made directly by Astellas for the benefit of a Recipient. Indirect ToVs are those made on behalf of Astellas for the benefit of a Recipient, or those made through a Third Party and where Astellas knows or can identify the Recipient that will benefit from the Transfer of Value.

- **Research and Development (R&D):** Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Regulation 536/2014); or (iii) Non-interventional Studies (NIS) 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.

In case of differences between the EFPIA reporting template and the Spanish Code of Good Practices for the Pharmaceutical Industry for categorisation of transfers of value, the methodology below reflects the EFPIA terminology used within the standard EFPIA template.

### 3. DATA PRIVACY

- 3.1 Astellas fully supports the principles of transparency and abides by data privacy law. Data privacy law requires Astellas to obtain permission from individual HCP prior to disclosing individual Transfers of Value to them. Astellas makes every effort to obtain, and maintain a record of, the necessary permissions. Astellas' approach for HCP consent is 'all in' or 'all out'. In other words, the consent decision is not specific to a transaction or activity but applicable to the HCP data will be removed or amended from the publication on the Company's webpage/regulatory platform and/or our database or other platforms as soon as reasonably practicable from the date the HCP decision to withdraw consent is communicated to us.
- 3.2 Where HCP do not give permission to such individual Disclosures, Astellas discloses the total amount of all Transfers of Value in the relevant category as an aggregate figure.
- 3.3 Disclosures must remain in the public domain for a minimum of three years and Astellas will document all Disclosures and retain the records for at least seven years.

### 4. TRANSFERS OF VALUE

- 4.1 Astellas discloses the following Transfers of Value it makes to **HCOs**:
- **Donations:** Funding (or benefits in kind) provided to HCOs for unspecified use.
  - **Grants:** Funding or support provided to HCOs in response to a request to support a specific activity that provides educational benefit or enhances patient care.
  - **Congress and educational event sponsorship:** Expenses related to the sponsorship of HCOs as congress organisers and/or secretariats & third parties on behalf of HCOs in exchange for corporate benefits at an event (*e.g.*, booth space, hosting of a symposium, stands, advertising on programmes or banners and room hire or catering if paid on behalf of an HCO). This may also include activities such as preceptorships, where expenses are paid to HCOs for arrangement of educational events.
  - **Fees:** Transfers of Value that are fees for service resulting from or related to contracts between companies and institutions, organizations or associations of Healthcare Professionals under which such institutions, organizations or associations provide any type of services to a company or any other type of funding

not covered in the previous categories. Fees and Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts, under the 'Fees' and the 'Related expenses agreed in the fee for service or consulting contract' categories.

4.2 Astellas discloses the following Transfers of Value it makes to **HCPs**:

- **Congress and educational event registration fees:** Expenses related to the registration of an HCP to attend a congress or educational event.
- **Travel:** Expenses related to the provision of travel to HCPs in relation to a fee for service contract (*e.g.*, rail travel, taxi travel, flights, reimbursement of private car miles) or to their attendance at a congress or educational event. Where travel expenses are required for the provision of a fee for service, these will be disclosed in the category of 'Related expenses agreed in the fee for service or consulting contract'. Where there is no provision of services and they relate to contribution costs of a congress or educational event they will be disclosed in the category of 'Travel and accommodation'.
- **Accommodation:** Expenses related to the provision of overnight accommodation of HCPs in relation to a fee for service contract or to their attendance at a congress or educational event. These will be disclosed in the category of 'Related expenses agreed in the fee for service or consulting contract' where they are required for the provision of expert advice and a fee for service. Where there is no provision of services and they relate to contribution costs of a congress or educational event they will be disclosed in the category of 'Travel and accommodation'.
- **Fees:** Transfers of Value paid to Healthcare Professionals to provide services to Astellas. These may include advisory board services, speaker services or other consulting services. Fees and Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts, under the 'Fees' and the 'Related expenses agreed in the fee for service or consulting contract' categories.
- In respect of each Transfer of Value described above, Astellas will disclose details only if a HCP/HCO actually receives the benefit of the transfer. For example, Astellas will not disclose a transfer relating to a flight intended to be taken by a HCP in relation to a fee for service contract if the HCP does not in fact take the flight, even if a cost is incurred by Astellas. On the other hand, Astellas will disclose a Transfer of Value if the HCP incurred the cost of the flight he/she was going to take and was directly reimbursed by Astellas.

4.3 Astellas discloses Transfers of Value to HCPs and HCOs that relate to **research and development** in the aggregate figure. These include expenses associated with clinical trials, non-clinical studies, non-interventional studies and investigator sponsored research.

- 4.4 Where Astellas makes a Transfer of Value to a HCP indirectly via a HCO, it discloses such transfer only once.
- 4.5 Where services for Astellas are rendered by an HCP on behalf of an HCO (for example, Astellas enters into a service contract with an HCO and the services are provided by the HCO's employee), the associated fees and expenses paid by Astellas to the HCO are disclosed as Transfers of Value made to the HCO. This is the case unless Astellas can confirm that the HCP received a benefit from the Transfer of Value, either directly from Astellas or via the HCO, (e.g., fees paid to the HCP in connection with the services he/she rendered and/or reimbursement of any related expenses the HCP incurred), in which case Astellas discloses those Transfers of Value as being transfers to the HCP. Where Astellas can identify the HCP and know that the HCO will make the full Transfer of Value to the HCP on Astellas' behalf, the Transfer of Value is disclosed as being a Transfer of Value to the HCP.
- 4.6 Where services are provided by a self-incorporated company set up by a HCP and the HCP is not the sole director of the company, Astellas will consider the recipient as an HCO and disclose the Transfer of Value to the HCO.

## **5. HCP AND HCO IDENTIFIERS**

- 5.1 Astellas identifies each HCP and HCO with a unique identification number. This unique identifier contains all the relevant information, including their names, surnames, national identity document and professional addresses, all with the aim of avoiding any confusion with the SP that has received the Transfer of Value.
- 5.2 Astellas identifies each meeting/event with a unique identification number.

## **6. COLLECTION, OBTENTION AND SEARCH OF INFORMATION**

- 6.1 Astellas includes any Transfer of Value made to HCPs/HCOs in a European Customer Management (CRM) tool, in different categories, not only those Transfers of Value to be published, but any Transfer of Value in favor of HCPs/HCOs (i.e. meals and/or other expenses)
- 6.2 All Transfers of Value collected are processed and analyzed before disclosing them, taking the specific amounts from various systems:
- Direct Transfers of Value: the amounts come from the SAP system.
  - Indirect Transfers of Value: amounts come from reports made by the third party (supplier, travel agent) acting on behalf of Astellas, and include the unique identification numbers of the PS/OS and the unique identification number of the meeting.

## **7. WHEN THE TRANSFER OF VALUE TAKES PLACE**

- 7.1 Astellas will disclose all Transfers of Value executed between January 1 and December 31 of each year, before June 30 of the following year.
- 7.2 For direct Transfers of Value (those paid directly by Astellas), the Transfer of Value takes place on the date Astellas pays for the service to the HCP/HCO. For example, if

Astellas engages a HCP to deliver a speech in December 2019 and those services were paid for in January 2020, Astellas will disclose the Transfer of Value in the 2020 transparency report.

- 7.3 For indirect Transfers of Value (those made by third parties), the Transfer of Value takes place on the date the service occurred. For example, if Astellas subsidizes a HCP travel and accommodation to attend a conference in December 2019 and Astellas pays the third party's invoice in January 2020, Astellas will disclose this Transfer of Value in the 2019 transparency report.
- 7.4 In no case will Astellas post any Transfer of Value (direct or indirect) that has not been completed and paid for by Astellas.

## 8. COUNTRY AND LANGUAGE OF DISCLOSURE

- 8.1 Astellas discloses Transfers of Value based on the HCP/HCO's principal place of practice. If the HCP/HCO operates in more than one country, Astellas will select one country to be the principal place of practice and disclose Transfers of Value in that country.
- 8.2 If any interaction made by Astellas with a Spanish HCP/HCO takes place outside the country in which the Recipient carries out its professional activity or has its legal address ("cross-border interaction"), this will be included in the Transfer of Value in the Report of Transparency of Spain. For example, all Transfers of Value made by Astellas, regardless of where the Astellas affiliate is located (eg transfers of value made by Astellas affiliates outside of Spain) will be included in the Spain Transparency Report.
- 8.3 The transparency report will be available in Spanish and English.
- 8.4 The report will be available on the local Spanish website [www.astellas.es](http://www.astellas.es)

## 9. CURRENCY

Astellas discloses Transfers of Value to HCPs and HCOs who operate in Spain in Euros (€). Where Transfers of Value are made in a currency other than **Euros**, the amount will be converted into **Euros** using an annual exchange rate. Amounts disclosed in **Euros** may therefore vary slightly from the exact amount paid in the local currency.

## 10. TIMING

Astellas discloses all Transfers of Value it makes between 1 January and 31 December of one year by 30th June of the following year. A Transfer of Value is made when the transfer is complete (*e.g.*, on payment date or transfer of value date). For example, if a contract is signed on 1 October 2021 but the payment is made on 31 January 2022, the Disclosure will be published by end June 2023.

## 11. AMOUNT

- 11.1 Astellas discloses the full amount of all Transfers of Value **exclusive** of VAT. Sometimes, in the case of indirect transfers of value, VAT may not be pulled apart, in those cases VAT will be included in the disclosed amount.

- 11.2 Astellas discloses the total amount including personal income tax withholdings.
- 11.3 Transfers of Value to HCPs reflect fair market value, taking into account the nature of services rendered, the amount of time spent, and the knowledge and expertise of the HCP.
- 11.4 When Astellas is party to a co-promotion agreement, Astellas discloses only Transfers of Value made by Astellas.

## **12. COMPLAINT PROCESS**

- 12.1 Astellas has created a Complaint Process that describes the process for resolving any complaint made by Healthcare Professionals ("HCPs") or Healthcare Organizations ("HCOs") related to information subject to disclosure by Astellas as required by the EFPIA Transparency Code and the Spanish Code of Good Practices for the Pharmaceutical Industry.
- 12.2 Any complaint received by any Astellas employee, whether by call or email from the HCP/HCO, should be forwarded to: [sp.transparency.dispute@astellas.com](mailto:sp.transparency.dispute@astellas.com)

## **13. LEGAL NOTICE**

Astellas uses a combination of standardized automated procedures and manual data collection through internal and external resources to obtain relevant information for disclosure. The information is published in good faith and reflects our best efforts to comply with the provisions of the EFPIA Transparency Code and the Spanish Code of Good Practices for the Pharmaceutical Industry. In the event that, despite all our efforts to ensure that the publication accurately reflects the values of the transfers made, we have not been able to include accurate and complete information, we will investigate and provide an appropriate response in the event that the information is incorrect. The information published according to the requirements of the Code on this website will be used only to comply with the provisions of the Code. The data may not be used as a reference by tax authorities.