

2016 Methodology

DISCLOSURES OF TRANSFERS OF VALUE: SUMMARY OF METHODOLOGY

1. ASTELLAS'S COMMITMENT

1.1 Astellas is a member company of the European Federation of Pharmaceutical Industries and Associations ("EFPIA"). The EFPIA Disclosure Code 2014 (the "EFPIA Disclosure Code" [available here- link to 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 Malta by the PRIMA Code [available here –<http://transparency.efpia.eu/countries/18/16/Malta>.]

1.2 Astellas discloses all Transfers of Value to HCPs and HCOs in accordance with its commitment to the EFPIA Disclosure Code and PRIMA in Malta.

1.3 This note summarises the methodologies used by Astellas in preparing Disclosures in compliance with the EFPIA Disclosure Code.

2. DEFINITIONS

2.1 The EFPIA Disclosure Code defines the following terms:

- "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 Europe; or an organisation through which one or more HCPs provide services. This can also include a self-incorporated company set up by a HCP where the recipient is not the sole director of the company.
- "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 Europe.
- "Transfer of Value (ToV)": Direct and indirect transfers of value (in payments or kind, or otherwise made) in connection with the development and sale of prescription-only medicinal products for human use whether for promotional services or otherwise.
- "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)
- The categories of ToVs referred to in this methodology statement are in line with the terminology used in the EFPIA code. The titles of these categories may vary to the terminology used in the template prescribed in Malta by the PRIMA Code.

3. DATA PRIVACY

Astellas fully supports the principles of transparency and abides by data privacy law. Data privacy law requires Astellas to obtain permission from individual HCPs 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 for all transfers of value and a 'yes' decision is effective until withdrawn.

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's decision to withdraw consent is communicated to us. The removal of data will be effective for the most recently published reporting year and all reporting years going forward.

3.1 Where HCPs 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.

3.2. 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 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).
- Preceptorship sponsorship: Expenses paid to HCOs for the arrangement of a preceptorship event (e.g. room hire, lump sum for all arrangements).
- 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 a 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. Where they 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'. Where Wi-Fi is included within the total accommodation cost, it will be disclosed in this category.
- Advisory Board services: Fees paid to HCPs contracted to attend a closed meeting with Astellas to provide expert advice on potential developments and enhancements to improve the quality of healthcare and patient outcomes in a specific therapy area. These will be disclosed in the category of 'Fees'.
- Speaker services: Fees paid to HCPs contracted to provide speaker services (e.g., at a congress, symposium or internal training) by or on behalf of Astellas or delivering educational materials on behalf of Astellas. These will be disclosed in the category of 'Fees'.

- Consulting services: Fees paid to HCPs contracted to provide other consulting services to Astellas (e.g. medical writing, reviewing materials or filming). These will be disclosed in the category of 'Fees'.
 - 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. Astellas considers the following Transfers of Value to relate to research and development:
- Investigator / site fees: Fees paid to a HCP/HCO for investigator services and study sites to support the conduct of a company sponsored trial.
 - Investigator meeting registration, travel and accommodation: Expenses related to the registration of a HCP to attend an R&D related investigator meeting including travel and accommodation.
 - HCP meals & sundry: Expenses related to the provision of meals and refreshments to HCPs in relation to R&D meetings.
 - Site staff costs: Expenses paid to HCO associated with nurse, sub-investigator, independent investigator fees / costs not included in per-patient fee relating to R&D.
 - Advisory Boards services, consulting services, accommodation, and travel: Fees and expenses paid to a HCP/HCO in relation to research and development of company sponsored trials.
 - Expert meeting services: Fees paid to a HCP/HCO contracted to attend expert meetings in relation to research and development (e.g., Steering Committees for clinical trials, adjudication committees) for company sponsored trials.
 - Data Safety Monitoring Boards ("DSMBs"): Fees paid to HCPs contracted for their involvement in DSMBs (e.g. safety monitoring, study integrity) for company sponsored trials.
 - Ethics/Competent authority approval, pharmacy costs, laboratory services & analysis, and clinical trial insurance: Fees paid to a HCO to support a company sponsored trial.
 - Investigator sponsored research: Fees and expenses paid to a HCP/HCO for a non-company sponsored clinical trial, where the investigator independently approaches Astellas with a request to support its study.
- 4.4 The primary purpose of the Transfer of Value will determine the category in which it is reported (e.g., if Astellas invites a speaker to present at a congress and is consequently required to pay travel and accommodation in respect of the HCP's attendance at the event, the primary purpose of the Transfer of Value is a fee for service, not relating to attendance at a congress and educational event and will be disclosed against 'Related expenses agreed in the fee for service or consulting contract').
- 4.5 Where Astellas makes a Transfer of Value to a HCP indirectly via a HCO, it discloses such transfer only once.
- 4.6 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.
- 4.7 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. COUNTRY OF DISCLOSURE

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.