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ASTELLAS: Methodological note for HCP/HCO disclosure 2025

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Astellas is a member company of the European Federation of Pharmaceutical Industries and Associations (“**EFPIA**”). The EFPIA Code is implemented in Norway by the Association of the Pharmaceutical Industry in Norway’s Industry rules (Legemiddelindustriens Bransjeregler).

Astellas discloses all transfers of value to Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) in accordance with its commitment to the EFPIA Code and this note summarizes the methodologies used by Astellas in preparing disclosures in this regard.

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1. Definitions:

1.1 Recipients:

1.1.1 **Healthcare Professionals (HCPs):** A member of the medical, dental, pharmacy or nursing professions and any other person who, during their professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice and whose principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes:

1.1.1.1 any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and

1.1.1.2 any employee of a Member Company whose primary occupation is that of a practicing HCP but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

1.1.2 **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 HCP provide services. This can also include a personal services company.

If a healthcare organisation consists of only one health professional or other relevant decision maker, then it would be subject to the requirements in the Code regarding individual health professionals.

1.2 Kind of ToVs:

1.2.1 Astellas discloses the following ToVs it makes to **HCPs**:

- 1.2.1.1 **Congress and educational event registration fees:**
Expenses related to the registration of an HCP to attend a congress or educational event.
- 1.2.1.2 **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 "Contracted Services – Expenses." 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"
- 1.2.1.3 **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 'Contracted Services- Expenses' 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"
- 1.2.1.4 **Fees:** ToVs paid to HCPs or to provide services to Astellas. These may include advisory board services, speaker services or other consulting services. Fees and ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts, under the 'Contracted Services - Fees' and the "Contracted Services – Expenses" categories.

1.2.2 Astellas discloses the following ToVs it makes to **HCOs**:

- 1.2.2.1 **Donations and grants:** Funding, benefits in kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation, institution and the like to provide goods or services to the benefit of the pharmaceutical company in return. Donations and grants to individuals are prohibited. In general, donations

are physical items, services or benefits-in-kind which may be offered or requested. Grants are the provision of funds.

- 1.2.2.2 **Congress and educational event sponsorship:** Expenses related to the sponsorship of HCOs as congress organizers 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.
- 1.2.2.3 **Fees:** ToVs 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 ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts, under the 'Contracted Services Fees' and the 'Contracted Services Expenses' categories.

1.2.3 Research and Development: HCO or HCP transfers of value that relate to the planning and conduct of:

- 1.2.3.1 Non-clinical studies (as defined in OECD Principles on Good Laboratory Practice).
- 1.2.3.2 Clinical trials (as defined in Regulation 536/2014)
- 1.2.3.3 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).
- 1.2.3.4 Non- interventional studies that are retrospective in nature have also been included within aggregate disclosure for R&D in this reporting year.

2. Disclosure's Scope

2.1 Products concerned:

- 2.1.1 Direct and Indirect ToVs, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicines for human use.

2.2 Company concerned:

Not applicable

2.3 Excluded ToVs:

- 2.3.1 Ordinary course purchases and sales of medicines by and between a company and a health professional or a healthcare organisation.
- 2.3.2 Samples of medicines provided in accordance with regulatory requirements.

2.4 ToVs date:

- 2.4.1 Astellas discloses all transfers of value it makes between 1 January and 31 December of one calendar year by 30th June of the following calendar year.
- 2.4.2 A transfer of value (ToV) 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 2025 but the payment is made on 1 January 2026, the Disclosure will be published by the end of June 2027.

2.5 Direct ToVs date:

2.5.1 Direct ToVs are those made directly by a Member Company for the benefit of a Recipient.

2.6 Indirect ToVs:

- 2.6.1 Indirect ToVs are those made on behalf of a Member Company for the benefit of a Recipient, or ToVs made through an intermediate and where the Member Company knows or can identify the HCP/HCO that will benefit from the transfer of value (ToV).
- 2.6.2 Where Astellas makes a transfer of value to an individual HCP indirectly via a HCO, Astellas discloses such transfer only once and preferably against the HCP where possible.
- 2.6.3 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 via the HCO, (e.g., fees paid to the HCP in connection with the services they 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 knows 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, except as provided below.
- 2.6.4 Where services are provided by a third-party provider on behalf of several HCPs or HCOs (e.g., to provide national or regional educational meetings) and the recipient HCPs or HCOs cannot be individually identified, Astellas will disclose against the third-party provider.

2.7 Non-monetary ToVs

- 2.7.1 Examples include services provided to a recipient via a third party, Collaborative Working in the form of non-financial support such as editorial support for a publication, agency support or other types of non-financial support, services provided by Astellas personnel.

2.8 ToVs in case of partial attendance or cancellation and refunds

- 2.8.1 In respect of each transfer of value described above, Astellas will disclose details only if an HCP or HCO 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, they were going to take and was directly reimbursed by Astellas.
- 2.8.2 Astellas offsets refunds against the original transfers of value for an HCP or HCO.

2.9 Cross-border activities

- 2.9.1 Astellas discloses cross border transfers of value based on the HCP or HCO's principal place of practice and in line with the regulatory requirements.
- 2.9.2 If the HCP or 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.
- 2.9.3 Transfers of Value made by Astellas to Norway HCOs or HCPs, irrespective of where the Astellas entity is located (e.g., transfers of value made by Astellas entities outside of Norway) are included in the Norway disclosure report.

2.10 R&D

2.10.1 Astellas discloses transfers of value to HCPs and HCOs that relate to research and development in the aggregate figure. See Section 1.1 above for types of activities included in the disclosure under R&D.

2.11 Voluntary disclosure

2.11.1 Not applicable

3. Specific Considerations

3.1 Country unique identifier:

3.1.1 Astellas's system incorporates unique identifiers to ensure accurate tracking and management of HCP or HCO's data.

3.2 Self-incorporated HCP:

3.2.1 If a Healthcare Organisation (HCO) consists of only one health professional or other relevant decision maker, then it would be subject to the requirements in the Code regarding individual Healthcare Professionals (HCP).

3.2.2 Where services are provided by a personal service company set up by a HCP and the HCP is the sole director of the company, Astellas will consider the recipient as an individual HCP and disclose the transfer of value to the individual.

3.3 Multi-year agreements:

3.3.1 Where a contract for any transfer of value listed for an HCP or HCO runs for more than one year, Astellas will disclose transfers of value relative to the contract in the year the transfer of value was made (which may be different to the year in which the contract was agreed).

3.4 Country specificities:

- 3.4.1 When Astellas is party to a co-promotion agreement, Astellas discloses only transfer of value made by Astellas, except where the other contracting party is an HCP or HCO, in which case Astellas is responsible for disclosing all transfer of value in connection with the agreement.
- 3.4.2 When a country has a specific requirement, the local legislation process is followed.

3.5 Quality checks:

- 3.5.1 Astellas conducts data checks prior to publication, focusing on both individual transactions and the overall transfer of value. The company has a remediation process in place and reviews the transfer of value, analysing trends from year to year. Thorough checks are carried out to ensure accuracy.

4. Data protection legal basis

4.1 Consent collection:

- 4.1.1 Astellas fully supports the principles of transparency and abides by data privacy law and collects consent at the first point of engagement with all HCPs and HCOs. If consent is withdrawn, we will remove their personal information from our webpage and/or other platforms as soon as reasonably practicable from the date such decision is communicated to Astellas.
- 4.1.2 Where a country adopts the legitimate interest basis as the consent basis, transfers of values to all HCPs and HCOs will be reported individually.

4.2 Legitimate interests:

- 4.2.1 Astellas has determined that legitimate interest is the most appropriate ground for disclosing individual transfers of value. An appropriate privacy notice or a link to it is included in relevant contracts notifying individuals that the legal basis for disclosure is now legitimate interest. Where no such notice is included, the legal basis remains consent.
- 4.2.2 Where individuals exercise their rights under data privacy law to object to individual disclosure, a balancing test is conducted to assess whether there are compelling grounds for publishing the data that override the interests or the fundamental rights and freedoms of the objecting individual.
- 4.2.3 Where the outcome of the balancing test is in favour of the individual, 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 and will be included in aggregate.

5. Form of disclosure

5.1 Date of publication:

- 5.1.1 Astellas publishes the report by 30/06/2026.

5.2 Disclosure platform:

- 5.2.1 Astellas publishes the report on [Transparency Center | Astellas](#).

5.3 Disclosure language:

- 5.3.1 Astellas publishes the report in English and Norwegian.

6. Disclosure financial data

6.1 Currency:

- 6.1.1 Astellas discloses transfers of value to a Norway HCP or HCO in EUR. Where transfers of value are made in a currency other than EUR the amount will be converted into EUR using an annual exchange rate.

6.2 VAT included or excluded:

- 6.2.1 Where possible, Astellas discloses the full amount of all transfers of value exclusive of VAT. In some instances, where VAT may not be separable, VAT has been included in the disclosure amount

6.3 Calculation rules:

- 6.3.1 Where the service is provided to a recipient via a third party, Astellas discloses the amount the third-party invoices Astellas for the service or goods as reflecting the value of transfer.
- 6.3.2 Where the service is provided by Astellas personnel, Astellas discloses the value of the transfer as the amount the recipient would have paid for an independent service provider to render the same service. Astellas considers the nature and duration and other relevant factors relating to the services its personnel provided to the recipient and estimates what the recipient would have paid a third party for the same services. Astellas categorises and discloses these transfers of value as a donation.

7. Additional information:

- 7.1 Not applicable