



Anylam Pharmaceuticals Transparency Reporting Methodological Note

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DISCLOSURES OF TRANSFERS OF VALUE: SUMMARY OF METHODOLOGY

1. ALNYLAM'S COMMITMENT

- 1.1 In Belgium, there is legal transparency obligation that imposes pharmaceutical and medical devices companies, both Belgian and foreign to document and annually disclose on the platform Betransparent.be the premiums and benefits that they granted directly or indirectly to Healthcare Professionals (HCPs), Healthcare Organisations (HCOs) or Patient Organisations (POs) as from 1 January 2017 (the Belgian Sunshine Act).
- 1.2 Alnylam discloses all Transfers of Value to HCPs, HCOs and POs in accordance with its commitment to the Belgian Sunshine Act.,
- 1.3 This note summarises the methodologies used by Alnylam in preparing Disclosures in compliance with the Belgian Sunshine Act.

2. DEFINITIONS

2.1 The Belgian Sunshine Act 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.
- **“Patient Organisations (PO)”**: A not-for-profit organisation (including umbrella organisations to which they belong), mainly composed of patients and/or caregivers that represent and/or support the needs of patients and/or caregivers.
- **“Research and Development (R&D)”**: HCO/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).
 - Non-interventional studies that are retrospective in nature have also been included within aggregate disclosure for R&D.
- **“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.

2.2 The categories of ToVs referred to in this methodology statement are in line with the terminology used in the Belgian Sunshine Act.

3. DATA PRIVACY

3.1 Alnylam fully supports the principles of transparency and abides by data privacy law. In accordance with Art. 43, §1, 1°, Sunshine Act, disclosures are made on a nominative basis by individual therefore, it is not necessary the consent of the HCPs for disclosing their individual data. A notification has been given to HCPs to inform them that their data is being processed for disclosure purposes in accordance with the Sunshine Act.

3.2 HCP / HCO data will only be amended for errors or omissions to the disclosure data identified, either by Alnylam or by the HCP / HCO / PO. Once an enquiry has been made and an investigation completed, any amendments required will be made to the publication on the betransparent.be platform as soon as reasonably practicable.

3.3 Disclosures must remain in the public domain for a minimum of three years and Alnylam will document all Disclosures and retain the records for at least seven years.

4. TRANSFERS OF VALUE

4.1 Alnylam discloses the following Transfers of Value it makes to **HCOs**:

- **Donations:** Funding (or benefits in kind) provided to HCOs for unspecified use in response to a request to support a specific activity that provides educational benefit or enhances patient care.
- **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.

Note: all above disclosures will be made to the final beneficiary as required by the Belgian Sunshine Act.

4.2 Alnylam 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 or to their attendance at a congress or educational event (*e.g.*, rail travel, taxi travel, flights, reimbursement of private car miles). 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’.
- **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’.
- **Scientific meetings organised by Alnylam:** Expenses related to speaker fees, meeting room rental and logistical arrangements (including time spent by Alnylam personnel to arrange meetings) has been allocated and disclosed as a benefit in kind against individual HCPs attending.
- **Fees:** Transfers of Value paid to Healthcare Professionals to provide services to Alnylam. 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.
 - Note: all above disclosures will be made to the final beneficiary as required by the Belgian Sunshine Act.

4.3 Alnylam discloses the following Transfers of Value it makes to **POs**:

- **Fees:** Transfers of Value paid to POs to provide services to Alnylam *e.g.*, 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.
- **Financial & Other Supports to POs:** Funding (or benefits in kind) provided to POs in response to a request to support a specific activity that enhances patient care.

4.4 In respect of each Transfer of Value described above, Alnylam will disclose details only if a HCP/HCO/PO actually receives the benefit of the transfer. For example, Alnylam 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 Alnylam. On the other hand, Alnylam 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 Alnylam.

- 4.5 Alnylam discloses Transfers of Value to HCPs and HCOs that relate to research and development in the aggregate figure in compliance with the Belgian Sunshine Act. These include expenses associated with clinical trials, non-clinical studies, non-interventional studies and investigator sponsored research.
- 4.6 Where Alnylam makes a Transfer of Value to a HCP indirectly via a HCO, it discloses such transfer only once pro rata upon the final beneficiary as required by the Belgian Sunshine Act.
- 4.7 Where services for Alnylam are rendered by an HCP on behalf of an HCO (for example, Alnylam 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 Alnylam to the HCO are disclosed as Transfers of Value made to the HCO. This is the case unless Alnylam can confirm that the HCP received a benefit from the Transfer of Value, either directly from Alnylam 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 Alnylam discloses those Transfers of Value pro rata as being transfers to the HCO and the HCP. Where Alnylam can identify the HCP and know that the HCO will make the full Transfer of Value to the HCP on Alnylam' behalf, the Transfer of Value is disclosed as being a Transfer of Value to the HCP as mandated by the Belgian Sunshine Act.
- 4.8 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, Alnylam will consider the recipient as an HCO and disclose the Transfer of Value to the HCO where this would be acceptable according to the Belgian Sunshine Act. If not, Alnylam will disclose against the respective HCPs.

5. COUNTRY OF DISCLOSURE

6. CURRENCY

- 6.1 Alnylam discloses Transfers of Value to Belgian HCPs, HCOs and POs in Euros. Where Transfers of Value are made in a currency other than Euro the amount will be converted into Euro using an annual exchange rate. Amounts disclosed in Euros may therefore vary slightly from the exact amount paid in the local currency.

7. TIMING

- 7.1 Alnylam discloses all Transfers of Value it makes between 1 January and 31 December of one year by 31st May 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 2019 but the payment is made on 1 January 2020, the Disclosure will be published by end June 2021.

8. MULTI-YEAR CONTRACTS

- 8.1 Where a contract for any Transfer of Value listed in Section 4, runs for more than one year, Alnylam will disclose Transfers of Value relating to that contract in the year the Transfer of Value was made (which may be different to the year in which the contract was agreed).

9. AMOUNT

- 9.1 Where possible, Alnylam discloses the full amount of all Transfers of Value exclusive of VAT. In some instances, for indirect transfers of value, VAT may not be separable, in these cases, VAT has been included in the disclosure amount.
- 9.2 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.
- 9.3 When Alnylam is party to a co-promotion agreement, Alnylam discloses only Transfers of Value made by Alnylam.
- 9.4 Transfer of Value made by Alnylam, irrespective of where the Alnylam entity is located (e.g. transfers of value made by Alnylam entities outside of Belgium) are included in the Belgian Disclosure report as mandated by law.