

# **Anylam Pharmaceuticals Transparency Reporting Methodological Note - Sweden**

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# DISCLOSURES OF TRANSFERS OF VALUE: SUMMARY OF METHODOLOGY

## 1. INTRODUCTION

Alnylam Pharmaceuticals Sweden has voluntarily agreed to abide by the EFPIA Code and supports the efforts of the Läkemedelsbranschens Etiska Regelverk (LER) / Ethical Rules for the Pharmaceutical Industry in Sweden [available here – [www.lif.se](http://www.lif.se)]. to increase transparency in the pharmaceutical industry.

This methodological note is intended to accompany Alnylam Pharmaceuticals Sweden's disclosure of transfers of value ("ToV") to Swedish HCPs and HCOs. It provides guidance on how Alnylam Pharmaceuticals Sweden has recorded and reported this data. All data in the disclosure report was correct at time of publication.

- 1.1 Alnylam discloses all Transfers of Value to HCPs and HCOs in accordance with its commitment to the Läkemedelsbranschens Etiska Regelverk (LER) / Ethical Rules for the Pharmaceutical Industry in Sweden and in line with the EFPIA Disclosure Code.
- 1.2 This note summarises the methodologies used by Alnylam in preparing Disclosures in compliance with the Ethical Rules for the Pharmaceutical Industry in Sweden.

## 2. DEFINITIONS

- 2.1 The Läkemedelsbranschens Etiska Regelverk (LER) / Ethical Rules for the Pharmaceutical Industry in Sweden defines the following terms:
  - **"Healthcare Organisation (HCO)":** means any legal person or sole trader which performs healthcare services or research or educational services within this field, or an organization with a medical or scientific purpose, with the exception of such organizations including politicians, user organisations, interest groups and the general public.
  - **"Healthcare Professional (HCP)":** A physician, dentist, pharmacist, nurse or any other natural person within healthcare or a government agency who has a right to prescribe, purchase, supply, recommend or administer a medicinal product, including employees of a pharmaceutical company whose primary occupation is that of a practicing healthcare personnel. All other employees of a pharmaceutical company or employees of a distributor of medicinal products are excluded from the definition of healthcare personnel.
  - **"Transfer of Value (ToV)":** Shall mean the direct and indirect transfers of value, whether in cash or in kind, which takes place in connection with the development or sale of medicinal products exclusively for human use, irrespective of whether or not the purpose is promotional. Direct transfers of value are those made directly by a pharmaceutical company to or for the benefit of a recipient. Indirect

transfers of value are those made on behalf of a pharmaceutical company by a third party (e.g., a subcontractor, a cooperation partner or affiliate) to or for the benefit of a recipient, provided that the pharmaceutical company knows or can identify the recipient.

- **“Research and Development (R&D)”**: HCP/HCO transfers of value that relate to the planning and conduct of:
    - o Non-clinical studies (as defined in OECD Principles on Good Laboratory Practice);
    - o Clinical trials (as defined in Directive 2001/20/EC);
    - o 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);
    - o Non-interventional studies that are retrospective in nature have also been included within aggregate disclosure for R&D in this reporting year; this has been included within the self-certification submitted to EFPIA for 2017.
- 2.2 In the case of differences between the categorisation of transfers of value in the EFPIA reporting template and template prescribed by the Läkemedelsbranschens Etiska Regelverk (LER) / Ethical Rules for the Pharmaceutical Industry in Sweden, the methodology below reflects the Swedish Ethical Rules for the Pharmaceutical Industry.

### 3. DATA PRIVACY

- 3.1 Alnylam fully supports the principles of transparency and abides by applicable data protection laws. Data protection laws require Alnylam to obtain permission from individual HCPs prior to disclosing individual Transfers of Value to them. Alnylam makes every effort to obtain, and maintain a record of, the necessary permissions. Alnylam’ 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.
- 3.2 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.
- 3.3 Where HCPs do not give permission to such individual Disclosures, Alnylam discloses the total amount of all Transfers of Value in the relevant category as an aggregate figure.
- 3.4 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.
- 3.5 Where payments are made to a self-incorporated HCP, consent must be provided in order to disclose the payments against the self-incorporated HCP. Where consent is not provided, payments to a self-incorporated HCP will be disclosed in the relevant category as an aggregate figure.

## 4. TRANSFERS OF VALUE

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

- **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). 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.

- **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.
- **Donations:** Funding (or benefits in kind) provided to HCOs to support research and development.

### 4.2 Alnylam discloses the following Transfers of Value it makes to HCPs:

- **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).

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'.

- **Accommodation:** Expenses related to the provision of overnight accommodation of HCPs in relation to a fee for service contract. These will be disclosed in the category of 'Related expenses agreed in the fee for service or consulting contract'.
- **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.

### 4.3 Alnylam 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 Alnylam makes a Transfer of Value to a HCP indirectly via a HCO, it discloses such transfer of value against the relevant HCO unless Alnylam knows that the HCO will make the full transfers of value to the HCP in which case it will be disclosed under the HCP.
- 4.5 Where services for Alnylam are rendered by a HCP on behalf of an HCO (for example, Alnylam enters into a service contract with a 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.
- 4.6 Where services are provided by a self-incorporated company set up by a HCP, Alnylam will consider the recipient as an HCO and disclose the Transfer of Value to the HCO.

## **5. COUNTRY OF DISCLOSURE**

- 5.1 Alnylam discloses Transfers of Value based on the HCP/HCO's principal place of practice. If the HCP/HCO operates in more than one country, Alnylam will select one country to be the principal place of practice and disclose Transfers of Value in that country.

## **6. TIMING**

- 6.1 Alnylam discloses all Transfers of Value it makes between 1 January and 31 December of one year by 31 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 May 2021.

## **7. CURRENCY**

- 7.1 Alnylam discloses Transfers of Value to HCPs and HCOs who operate in Sweden in Swedish kronor (SEK). Where Transfers of Value are made in a currency other than SEK, the amount will be converted into SEK using an annual exchange rate. Amounts disclosed in SEK may therefore vary slightly from the exact amount paid in the local currency.

## **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 contracts 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 Sweden) are included in the Disclosure report for Sweden.

## 10. DISCLOSURE PLATFORM

10.1 Disclosure reports will be published on Alnylam's global website <https://www.alnylam.com/about-alnylam/transparency>

In Sweden, Alnylam will provide a link to LIF Cooperation Database where the disclosure report is also published: <http://www.lif.se/etik/samarbetsdatabaser/C>