

# **Alnylam Pharmaceuticals Transparency Reporting Methodological Note**

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## 1. Introduction

Alnylam Pharmaceuticals UK has voluntarily agreed to abide by the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice and supports the efforts of the Association of the British Pharmaceutical Industry (ABPI) Code of Practice to increase transparency in the pharmaceutical industry.

This methodological note is intended to accompany Alnylam Pharmaceuticals UK's disclosure of Transfers of Value ("ToV") and other benefits in kind with UK HCPs, HCOs and ORDMs. It provides guidance on how Alnylam Pharmaceuticals UK has recorded and reported this data. All data in the disclosure report was correct at the time of publication.

Alnylam makes every effort to disclose Transfers of Value to HCPs HCOs and ORDMs in accordance with its commitment to the EFPIA Disclosure Code and the ABPI Code of Practice.

This note summarises the methodologies used by Alnylam in preparing disclosures in compliance with the EFPIA Disclosure Code and the ABPI Code of Practice.

## 2. Definitions

The ABPI 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 or ORDMs 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.
- **Other Relevant Decision Makers (ORDM):** Those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not health professionals.

- **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 in this reporting year.
- **Third Party:** This means a legal person/entity or individual that represents a company or interacts with other parties on behalf of a company or relating to a company's medicine, such as distributors, wholesalers, consultants, contract research organisations, professional congress organisers, contracted sales forces, market research companies, advertising agencies, media buyers, providers of services related to events, public relations services, non-clinical services, non-interventional studies management services etc.
- **Transfer of Value (ToV):** Direct and indirect ToV (in payments or kind, or otherwise made) in connection with the development or sale of prescription-only medicinal products for human use whether for promotional services or otherwise.

### 3. Transfers of Value

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

- a. **Donations and Grants.** Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare (governed by Article 12 of the EFPIA Code).
- b. **Contribution to costs related to Events.** Contribution to costs related to Events, through HCOs or third parties, including sponsorship to HCPs to attend Events, such as:
  - i. Registration fees.
  - ii. Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event; and
  - iii. Travel and accommodation (to the extent governed by Article 10 of the EFPIA Code).

- c. **Fees for Service and Consultancy.** ToV resulting from or related to contracts between Member Companies and institutions, organisations or associations of HCPs under which such institutions, organisations or associations provide any type of services to a Member Company, or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToV relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

### 3.2. Alnylam discloses the following Transfers of Value it makes to HCPs & ORDMs:

- a. **Congress and educational event registration fees:** Expenses related to the registration of a HCP or ORDM to attend a congress or educational event.
- b. **Travel:** Expenses related to the provision of travel to HCPs or ORDMs 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'.

- c. **Accommodation:** Expenses related to the provision of overnight accommodation of HCPs or ORDMs 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'.
- d. **Meals and refreshments:** Directly reimbursed expenses related to the provision of meals and refreshments to HCPs or ORDMs in relation to their sponsorship for attendance at a congress or educational event will not exceed the mandated threshold of £75 per person, excluding VAT and gratuities. Such expenses will not be disclosed as stated by the ABPI Code.
- e. **Fees:** ToV paid to Healthcare Professionals to provide services to Alnylam. These may include advisory board services, speaker services or other consulting services. Fees and ToV 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.
- f. 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 **HCP** are disclosed as Transfers of Value made to the **HCP** when consent has been collected. If consent was not collected, Alnylam will report these associated fees and expenses under the **HCO**.

### **3.3. Alnylam discloses Transfers of Value to HCPs and HCOs that relate to Research and Development**

R&D includes ToVs related to pre-clinical and clinical development, paid to an HCO or an HCP directly or indirectly (for example through a CRO or third-party vendor).

All R&D ToVs are aggregated by country as a single number based on the recipient's country's principal practice address in the disclosure report. In case ToV relating to prospective and retrospective non-interventional studies cannot be distinguished, all non-interventional studies are disclosed on an individual basis under fee for service, where consent allows.

### **3.4. Market Research**

Where the identity of an HCP participating in a market research project is known to Alnylam a ToV disclosure will be made at the individual HCP level.

### **3.5. Fee Payments to Charities**

HCPs who have worked with Alnylam may ask for their fee to be paid to a charity. Alnylam does not encourage this type of fee payment and all payments are normally made directly to the HCP; where payment to a charity may occur, the disclosure is still made against the individual HCP.

### **3.6. Direct and Indirect Transfers of Values**

The disclosures include both direct and indirect ToV provided to recipients or for their benefit. In this context:

- Direct ToVs are provided to the recipient by our Company directly,
- Indirect ToVs are provided to the recipient through a third party. In this situation, our partners are required by contract to share with our Company all information relative to ToV in order to allow an appropriate preparation of the disclosure.

### 3.7. Out-of-Scope Transfers of Values

ToVs in the following categories are not included in the disclosed information:

- Activities solely related to over-the-counter pharmaceutical products,
- Items of medical utility,
- Meals and drinks,
- Travel expenses in line with the threshold applicable to meals and drinks,
- Medical samples,
- Commercial activities that are part of ordinary course purchases and sales of medicinal products, or any other ToV which is out of the reporting scope, as defined by the EFPIA and ABPI Codes of Practice.

There are no disclosures related to Medical Devices.

## 4. Consent Management

Alnylam fully supports the principles of transparency and abides by data privacy law. Data privacy law requires Alnylam to obtain explicit permission from individual HCPs or ORDMs prior to disclosing individual ToV to them. Alnylam makes every effort to obtain, and maintain a record of, the necessary permissions.

Where an HCP has not provided consent to disclose ToV, where Alnylam has not received a response on the issue of consent (and it is therefore assumed consent was not given) or where an HCP has withdrawn consent, ToV will be aggregated and disclosed. When declaring aggregated ToV, the total number of HCPs and total aggregated sum will be disclosed.

Where an HCP runs a limited company for the purposes of receiving private income, ToV to that organisation have been disclosed as a ToV to that HCP wherever possible. Where a payment is made to a larger organisation (e.g., a university), Alnylam will disclose the ToV against the organisation.

HCPs remain free to withdraw their consent for disclosure of data at any time by notifying Alnylam in writing and an HCPs decision on consent to disclose will not impact Alnylam's willingness to work with them.

- In the event that an HCP revokes consent prior to submission of data Alnylam will update the data and include the ToV for the corresponding HCP as aggregated.

- In the event that an HCP revokes consent after submission of the data, Alnylam will attempt to remove the personal data concerning ToV of the corresponding HCP as soon as possible.

## **5. Cross-border Activities**

Alnylam UK has included details of cross border ToV from engagements made by Alnylam affiliates outside of the UK-to-UK HCPs.

All ToV will be declared in British Pounds Sterling (£GBP). Where ToV was made in other currencies, Alnylam UK will convert these into £GBP using the appropriate daily exchange rate.

## **6. Disclosure of Financial Data**

### **6.1. ToV Currency Approach**

Alnylam discloses ToV to UK HCPs, HCOs and ORDMS in UK currency the pound sterling Great British Pounds (£GBP). Where ToV are made in a currency other than GBP the amount will be converted into GBP using an exchange rate as on the date of payment. Amounts disclosed in GBP may therefore vary slightly from the exact amount paid in the local currency.

### **6.2. VAT**

Where possible, Alnylam discloses the full amount of all ToV exclusive of VAT. In some instances, VAT may not be separable, in these cases, VAT has been included in the disclosure amount.

Where payment of taxes is due, they are the responsibility of the recipient of the ToV and not Alnylam Pharmaceuticals UK.

## **7. Publication**

In line with the ABPI, disclosures are made annually and the publication relates to the previous calendar year from 1<sup>st</sup> January to 31<sup>st</sup> December. This information will remain available in the public domain for a period of three (3) years after the date of the publication.

ToV will be declared according to the year in which the payment or transfer takes place, that is the date of the wire transfer to the recipient occurs as opposed to the date of the event or supporting agreement.



In the event that Alnylam arranges and incurs costs for travel and accommodation for an event that is subsequently cancelled (e.g., due to illness) with the result that the HCP does not 'use' the travel and accommodation, this will not classify as a ToV and will therefore not be disclosed.

For reporting ToV relating to agreements that span multiple years, Alnylam will disclose ToV based on date of payment as outlined above.

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Enquiries relating to Alnylam Pharmaceuticals UK's transparency reports should be addressed to [UKDisclosure@alnylam.com](mailto:UKDisclosure@alnylam.com).