

Anylam Pharmaceuticals Transparency Reporting Methodological Note - Luxembourg

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DISCLOSURES OF TRANSFERS OF VALUE: SUMMARY OF METHODOLOGY

1. INTRODUCTION

Alnylam Pharmaceuticals Luxembourg has voluntarily agreed to abide by the EFPIA Code and supports the efforts of the IML Innovative Medicines for Luxembourg (IML) to increase transparency in the pharmaceutical industry.

This methodological note is intended to accompany Alnylam Pharmaceuticals Luxembourg's disclosure of transfers of value ("ToV") to Luxembourgish HCPs and HCOs. It provides guidance on how Alnylam Pharmaceuticals Luxembourg 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 IML 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 Luxembourg.

2. DEFINITIONS

2.1 IML for the Pharmaceutical Industry in Luxembourg defines the following terms:

- **Healthcare Organisation (HCO):** Any association or organisation active in the healthcare, medical or scientific field, regardless of its legal or organisational form, as well as any legal entity through which one or more Healthcare Professionals provide services, with the exception of Patient Organisations.
- **Healthcare Professional (HCP):** Any natural person practising medical, dental, pharmaceutical or nursing art who, as part of their professional activities, may prescribe, purchase, deliver, recommend, lease, use or administer medicines or medical devices.
- **"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 Innovative Medicines for Luxembourg / Ethical Rules for the Pharmaceutical Industry in Luxembourg, the methodology below reflects the Luxembourgish 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's 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:

Donations and grants that support healthcare, including donations and grants, whether in cash or in kind, to institutions, organisations or associations made up of Healthcare Professionals and/or that provide healthcare, referred to in Article 16 of the IML Code.

Contributions towards the costs of scientific events, including sponsorship offered to Healthcare Professionals for the purpose of participating in these events, such as:

- Registration fees;
- Sponsorship agreements with health sector organisations or with third parties appointed by these organisations to manage a scientific event; and
- Travel, meal and accommodation expenses as referred to in Article 29 of the IML Code.

Fees for services and consultancy. This category includes Transfers of Value resulting from or related to contracts between Member Company and institutions, organisations or associations of Healthcare Professionals according to which these institutions, organisations or associations provide a service to a Member Company, as well as any other type of financing not covered by the previous categories. Fees and Value Transfers relating to reimbursements of expenses agreed in the written agreement covering the activity will be published separately.

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

Registration fees; and travel, and accommodation expenses as referred to in Article 29 of the IML Code.

Fees for services and consultancy. This category includes Value Transfers resulting from or related to contracts between Member Company and Healthcare Professionals under which the latter provide a service to a Member Company, as well as any other type of financing not covered by the previous categories. Fees and Transfers of Value relating to reimbursements of expenses agreed in the written agreement covering the activity will be published separately.

- 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 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 30 June 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 Luxembourg in EURO (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. Amounts disclosed in EUR 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 Luxembourg) are included in the Disclosure report for Luxembourg.

10. DISCLOSURE PLATFORM

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