



EFPIA DISCLOSURE METHODOLOGICAL NOTE

Version: 01; this document replaces previous drafts and versions

Effective date: 29.03.2019

1 Introduction

Collaborations between pharmaceutical companies and healthcare professionals and healthcare organisations play a crucial role in the development of new medicines and improvement of patient care. AveXis is committed to ensuring that its interactions meet the highest standards of integrity and transparency expected by patients, governments, society and other stakeholders. For this reason, AveXis publishes details of its transfers of value to healthcare professionals and healthcare organisations in accordance with the EFPIA Code on Disclosure of Transfers of Value From Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (EFPIA Disclosure Code)¹ and the code of the EFPIA member association in the respective country (as specified in Appendix A).

2 Purpose of this Methodological Note

This EFPIA Disclosure Methodological Note summarizes how AveXis generally recognises, classifies and reports transfers of value across all EFPIA countries. It is supplemented by an appendix that sets out country-specific details and deviations to the general methodology applied when preparing the disclosure report for the country identified in Appendix A (see Appendix A: Country Specific Considerations).

For information on the country-specific considerations applied in preparing other disclosure reports, please consult the respective EFPIA Disclosure Methodological Note on AveXis' website.

3 Definitions

The following terms are used throughout this document:

3.1 Transfers of Value (ToVs)

Direct and indirect Transfers of Value (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 medicinal products exclusively for human use.

Direct ToVs are those made directly by AveXis to the benefitting Recipient.

Indirect ToVs are those made on behalf of AveXis to the benefitting Recipient, or ToVs made through an intermediary (e.g. a meeting organiser or travel agent) and where AveXis is able to identify the benefitting Recipient.

¹ Please visit <http://transparency.efpia.eu> for further details

3.2 Recipients

A Recipient is any healthcare professional and healthcare organisation to which AveXis makes a ToV. For reporting purposes, Recipients are considered to be in the country where they have their main practice, principal professional address or place of incorporation.

Recipients can be further classified as Healthcare Professionals and Healthcare Organisations:

A Healthcare Professional (HCP) is defined as any natural person who is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product.

A Healthcare Organisation (HCO) is any legal person that is a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations), or through which one or more HCPs provide services.

3.3 Research and Development

Research and Development ToVs are those made to HCPs or HCOs related to the planning and conduct of:

- Non-clinical studies (as defined in the OECD Principles of GLP);
- Clinical trials (as defined in Directive 2001/20/EC); or
- 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 (Section 15.02 of the EFPIA HCP Code).

4 Form of Disclosure

4.1 Time and Duration of Publication

ToVs are disclosed on an annual basis and within six months after the end of the calendar year. The disclosure report remains in the public domain for a minimum of three years.

4.2 Platform

The disclosure report is published on AveXis' website. In case the applicable national code requires disclosure on an external central platform, AveXis provides a link to the external source where the disclosure report is published.

4.3 Language

The disclosure report is in the local language of the Recipients' country of primary practice or incorporation.

5 Disclosure Details

5.1 Covered Entities

AveXis was acquired by Novartis in 2018, but decided to disclose its ToVs as a separate entity.

5.2 Cross-Border ToVs

ToVs are disclosed in the country where the Recipient has its main practice, principal professional address or place of incorporation, irrespective of the place of incorporation of the AveXis entity making the ToVs or the place where the event took place or service was provided.

5.3 Excluded Transfers of Value

The following ToVs are not included in the disclosure report because they fall outside of the scope of the disclosure requirements:

- ToVs solely related to over-the-counter medicines

- ToVs excluded from the scope of the EFPIA Disclosure Code, such as informational and educational materials, items of medical utility, food and beverages and medical samples
- Fees charged by logistics agencies assisting in organising travel and meetings
- Payments or pricing adjustments that are a normal part of the purchase and sale of medicinal products, such as discounts and price reductions

5.4 Direct and Indirect Transfers of Value

AveXis discloses direct and indirect ToVs. In general, indirect ToVs are reported at the level of the first identifiable recipient which falls under the definition of an HCP/HCO. Each ToV is disclosed only once to avoid duplication.

5.5 Transfers of Value Date

The disclosure report includes all ToVs whose date falls between 01 January and 31 December of the respective reporting year.

The ToV date is defined as the payment date for the following ToVs:

- Fee For Service and Consultancy: Fee
- Fee for Service and Consultancy: Expenses (reimbursed)
- Contribution to Cost of Events: Sponsorship Agreements with HCOs or with third parties appointed by an HCO to manage an Event
- Grants and Donations
- Research and Development

The ToV date is defined as the event date for the following ToVs:

- Fee for Service and Consultancy: Expenses (in-kind)
- Contribution to Cost of Events: Registration Fees
- Contribution to Cost of Events: Travel and Accommodation

ToVs for which relevant information is not available on time will be included in the next report.

For multi-year agreements or other agreements in which ToVs are provided in different calendar years, each ToV is disclosed according to the methodology described above.

5.6 Partial Attendance or Cancellation

Only ToVs that are actually received by the Recipient are included in the report. ToVs not received by the Recipient due to partial attendance or cancellation do not form part of the disclosure, even if a cost is incurred by AveXis.

6 Reporting Categories

AveXis applies the EFPIA Disclosure Code's definition of the reporting categories. The following table provides a non-exhaustive list of examples of the specific activities reported under each category.

Donations and grants to HCOs
<ul style="list-style-type: none"> - Charitable contributions - Donations for the purpose of supporting healthcare or research - Educational grants (e.g. independent educational programs) - Research grants (if not falling under the definition of Research and Development)
Contribution to costs of events
<p>Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event</p> <ul style="list-style-type: none"> - Funding an event in exchange for the placement of a brand logo in a conference program or invitation communication - Funding an event in return for a display booth or projection area at the event - Satellite symposia at a congress

- Funding or support of HCO website in return for space to publish educational or promotional content or link to AveXis' website
- Other advertisement space (in paper, electronic or other format)

Note: Catering costs are included in the disclosed ToV if they form part of the sponsorship package.

Registration fees

- Registration fees related to HCPs/HCOs attending a congress or symposia

Travel and accommodation

- Travel expenses related to HCPs/HCOs attending a congress or symposia (e.g. flight, train, taxi, mileage reimbursement, parking)
- Accommodation expenses related to HCPs/HCOs attending a congress or symposia

Note: Travel and accommodation costs related to services or research & development activities are included in the respective categories.

Fees for services and consultancy

Fees

- Speaker engagements
- Advisory boards and other consulting engagements
- Data analysis, medical writing and development of educational materials
- Market research (if identity of participant is known)
- Other research activities (if not falling under the definition of Research and Development)

Related expenses agreed in the fee for service or consultancy contract (including travel and accommodation relevant to the contract)

- Travel expenses related to the provision of a service (e.g. flight, train, taxi, mileage reimbursement, parking)
- Accommodation expenses related to the provision of a service

Note: Where expenses are immaterial or cannot be disaggregated from the service fee without unreasonable effort they are disclosed under "Fees for Services and Consultancy" category.

Research and development

- Fee for investigator activities related to research and development
- Funding of investigator initiated research
- Activities contracted to CROs, where indirect ToVs are made to HCPs/HCOs

Note: ToVs related to research & development are disclosed in aggregate form.

7 Consent Management

7.1 Consent Collection

Where required by applicable data privacy regulations, AveXis seeks to collect Recipients' explicit consent to the disclosure of personal data and individual ToVs.

AveXis strongly supports the principle of transparency and strives to maximize the proportion of ToVs disclosed on an individual basis. ToV are only disclosed in the aggregate section of the disclosure report if:

- The Recipient does not consent to the disclosure of the data
- The Recipient only grants consent to the disclosure of some and not all ToVs ("Cherry Picking")
- No response from the Recipient is received in time

7.2 Management of Requests and Consent Withdrawals

Consent is voluntary and can be withdrawn at any time. Recipients may contact AveXis at emeatransparency@avexis.com to withdraw consent or to request further information about, or corrections to, the published data.

Updates to the disclosure report are conducted on a regular basis to reflect data updates or consent withdrawal after disclosure submission.

8 Financial Considerations

8.1 Calculation Rules

ToVs to multiple Recipients (e.g. group transportation, sponsorship of event organised by more than one HCO) are separated and associated with individual HCPs/HCOs whenever possible. Where an exact disaggregation is not possible, the ToV is divided by the total number of recipients (including non-HCPs/HCOs).

8.2 Tax Aspects

Where possible, AveXis discloses ToVs excluding taxes and VAT. In some instances for indirect transfers of value, the disclosed amount includes taxes and VAT.

8.3 Currency Conversion

ToVs are disclosed in the currency of the Recipients' country of primary practice or incorporation. ToVs in foreign currencies are converted into this local currency using company-internal average annual exchange rates.

9 Other Considerations

9.1 Unique Identifiers

AveXis discloses the “Country Unique Identifier” for Recipients, where this is required by the applicable national code.

9.2 Self-Incorporated HCPs

ToVs to self-incorporated HCPs are either disclosed under the individual HCP or the HCP's company (i.e. HCO) depending on the underlying contract.



APPENDIX A: COUNTRY-SPECIFIC CONSIDERATIONS

To be read in conjunction with the *EFPIA Disclosure Methodological Note*

Country: Italy

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Topic	Section Reference	Description of Country-Specific Consideration
Applicable National Code	1	Farmindustria Code of Conduct