



ITALY

METHODOLOGICAL NOTE

on disclosure of transfers of value to healthcare professionals and organisations

(Information is stated as of 24 June 2016)

1. Introduction

“Collaboration between industry and health professionals benefits patients. It is a relationship that has delivered numerous innovative medicines and changed the way many diseases impact on our lives. Industry and health professionals collaborate in a range of activities from clinical research, sharing best clinical practice and exchanging information on how new medicines fit in to the patient pathway. Bringing greater transparency to this, already well-regulated, vital relationship is about strengthening the basis for collaboration in the future. Society has increasingly high expectations for transparency, none more so than in healthcare” (EFPIA).

Eisai wants to ensure it meets those expectations.

This note accompanies the disclosure made by Eisai under EFPIA and national pharma association codes on disclosure of Transfers of Value (ToV) from pharmaceutical companies to Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs). This note includes a general summary and any country specific considerations.

2. Definitions

Eisai recognises HCPs, HCOs and ToV according to the EFPIA or national pharma code definitions (where applicable) for the disclosure period.

3. Disclosure's scope

Eisai is disclosing ToV to HCPs and HCOs in countries where Eisai is present through an subsidiary or branch.

3.1 Excluded ToV

Eisai has concluded that certain ToV are not covered by EFPIA and national pharma codes and, therefore, have not included in them in this disclosure:

Commercial or Promotional ToV:

- ToV made by another company under a co-promotion agreement with Eisai are disclosed by the other company and not by Eisai.
- ToV paid as part of a market research study where Eisai does not know the identity of the participating HCPs or HCOs will be disclosed on an aggregated basis, if available.
- Event costs, such as the rental of equipment associated with one-off events e.g. room hire, projector rental, audio visual equipment.
- ToV made to a group of HCPs, such as group transportation e.g. bus chartering to an event will be disclosed on an aggregated basis, if available.

Research & Development ToV:

- Eisai lending laboratory equipment to a HCO as part of a study (where such activity is permitted under local pharma rules).

3.2 ToV date

Eisai discloses the ToV using the date the payment was made to the HCP or HCO.

3.3 Direct ToV

ToV can be made to the HCP or HCO directly e.g. payment to an HCP for giving expert advice in an Advisory Board.

3.4 Indirect ToV

ToV can be made to the HCP or HCO indirectly e.g. registration fees paid to a conference provider on behalf of an HCP.

When a third party is used to pay a HCP or HCO the information required for disclosure may be provided to Eisai by the third party and uploaded to the disclosure software. Where the ToV (net of agency fee) is known and consent to disclose has been given by the HCP, the value to the individual HCP / HCO will be disclosed. Otherwise the disclosure will be made in aggregate.

3.5 ToV in case of partial attendances or cancellation

In case of cancellation the ToV is not included in the disclosure.

In case of partial attendance the ToV is included in the disclosure.

3.6 Cross-border activities

Disclosures of ToV are made pursuant to the national code of the country where the HCP principally practices or where the HCO has its primary place of operation, whether the ToV occurs in or outside of that country.

If a HCP changes their country of practice then that information will be disclosed for the principal place of operation at the time of disclosure.

4. Specific considerations

4.1 Multi-year agreements

Any payments made against a multi-year contract are disclosed in the period covering the actual payment date.

4.2 Multiple HCO agreements

We disclose the amount paid to the Eisai ToV vendor set up our finance system

5. Consent management

Where HCP or HCO (where applicable) consent has been obtained, Eisai discloses ToV on an individual basis. Where HCP or HCO consent has not been obtained, Eisai discloses ToV on an aggregate basis. When consent is ambiguous we do not assume consent has been given and the ToV is disclosed on an aggregate basis.

5.1 Consent collection

Consent for individual disclosure was requested in each country. This was done on a contract by contract basis and/or as a one off request (where applicable).

5.2 Management of recipient consent withdrawal

Requests must be made in writing to infoprivacy@eisai.net or to Responsabile del Trattamento dei dati personali Eisai s.r.l., via dell'Unione Europea 6b, 20097 San Donato Milanese. When written requests are received Eisai updates the transparency reporting system to reflect the request. When consent is withdrawn the ToV are added to the aggregated ToV.

5.3 Management of recipient's request

Requests must be made in writing to infoprivacy@eisai.net or to Responsabile del Trattamento dei dati personali Eisai s.r.l., via dell'Unione Europea 6b, 20097 San Donato Milanese.

5.4 Partial consent

Where partial consent is obtained Eisai will disclose the total ToV in aggregate.

6. Disclosure Form

Where there is a centralised platform for disclosure Eisai uses that platform only. Where there is no centralised platform we shall publish on Eisai's own country website. The country disclosure template will be used where provided.

7. Disclosure financial data

7.1 Currencies

Disclosures are made in the local currency. Foreign exchange rates are based on published commercial rates used internally by Eisai. Exchange rates are applied to ToV based on the payment month of the ToV.

7.2 VAT included or excluded

ToV are disclosed VAT excluded, withholding tax included.

7.3 Calculation rules

Donations are disclosed using the fair market value (FMV) of the item.

