



UNITED KINGDOM

METHODOLOGICAL NOTE

on disclosure of Transfers of Value to Healthcare Professionals and Healthcare Organisations

(Information for Reporting of 2023 Data)

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1. Introduction

Eisai Limited (hereinafter referred to as “Eisai”) fully supports the transparency requirements in the Association of the British Pharmaceutical Industry (ABPI) Code of Practice and is committed to making public the details of all transfers of value (ToV) made to healthcare professionals (HCPs), other relevant decision makers (ORDMs) and healthcare organisations (HCOs).

This note describes the methods used by Eisai to meet the obligations for disclosing ToV made to HCPs, ORDMs and HCOs and this note includes a general summary of how Eisai collects and prepares this data.

2. Definitions

Eisai recognises HCPs, ORDMs, HCOs and ToV according to the ABPI Code of Practice for the disclosure period.

The term **Transfer of Value** means a direct or indirect payment, whether in cash, in-kind, or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. ToV include:

- collaborative working, including joint working
- donations and grants provided to healthcare organisations, institutions and other organisations
- fees and expenses paid for contracted services between companies and institutions, organisations or associations of health professionals
- support of attendance by health professionals and other relevant decision makers at events/meetings
- fees and expenses paid for contracted services to health professionals and other relevant decision makers, or to their employers on their behalf
- sponsorship, including contributions to costs related to events/meetings paid to healthcare organisations or to organisations managing events on their behalf, which may include support of health professionals not known to the company via the healthcare organisation by way of registration fees, accommodation and travel

The term **Healthcare Professional** includes members of the medical, pharmacy or nursing profession and any other person who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine.

The term **Other Relevant Decision Maker** include those in a role that could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply, or use of any medicine but who is not a HCP.

The term **Healthcare Organisation** means a healthcare, medical or scientific association or organisation such as 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.

3. Scope

3.1 Excluded ToV

Eisai has concluded that certain ToV are not covered by the EFPIA and the ABPI Codes of Practice, and therefore Eisai does not disclose such ToV.

Food and drink costs are excluded from ToV disclosed in respect of Eisai organised and sponsored meetings. However, for sponsored meetings, where Eisai specifically contributes towards subsistence as part of a sponsorship, this will be included in the ToV disclosed.

ToV made by another company under a co-promotion agreement with Eisai are disclosed by the other company and not by Eisai.

Event costs, such as the rental of equipment associated with one-off events (for e.g., room hire, projector rental, audio visual equipment) are excluded from ToV disclosed in respect of Eisai organised meetings. However, for sponsored meetings, where Eisai specifically contributes towards rental of equipment, this will be included in the ToV disclosed.

3.2 Aggregated ToV

Where Eisai receives and accepts an objection to disclose a ToV on the basis of Eisai's legitimate interests, the ToV will be aggregated. Aggregated ToV are ToV not publicly disclosed against an individual HCP/ORDM but are included in a lump sum of Eisai's HCP/ORDM ToV disclosure which have been anonymised.

Other examples of ToV which will be disclosed in aggregate include:

- ToV paid as part of a market research study where Eisai does not know the identity of the participating HCPs or ORDMs.
- All R&D ToV are aggregated as a single value. The ToV related to the planning and conduct of non-clinical studies, interventional clinical trials and non-interventional clinical studies conducted by Eisai or by Contract Research Organisations and other third parties on Eisai's behalf that are prospective in nature are included in the aggregate reporting.

3.3 ToV date

Eisai discloses the ToV based on the date the payment was made to the HCP, ORDM or HCO.

3.4 Direct ToV

Direct ToV are made directly by Eisai for the benefit of a to HCP, ORDM or HCO. (For e.g., a payment to an HCP for giving expert advice in an Advisory Board).

3.5 Indirect ToV

Indirect ToV are made on behalf of Eisai through an intermediate for the benefit of an HCP, ORDM or HCO i.e., through a third party working on behalf of Eisai. (For e.g., a

payment made to an HCP via a third-party agency, or registration fees paid by Eisai to a conference provider in respect of an HCP's registration fee for that conference).

Where an HCP or ORDM undertakes activities on behalf of an HCO, and where the HCO has been paid indirectly for this service, Eisai will make every effort to disclose against the individual HCP or ORDM.

Where a third party is appointed by an HCO to manage an event, and where the HCO benefits from that ToV, any such payments are disclosed against the HCO. If an event is organised on behalf of multiple HCOs and the actual amount per HCO cannot be ascribed, Eisai will split the total amount evenly and disclose against the individual HCOs.

3.6 ToV in case of partial attendances or cancellation

In the case of cancellation of a meeting or event, and where an HCP, ORDM or HCO does not receive a ToV, the ToV is not included in the disclosure.

In the case of partial attendance, any ToV received by an HCP or ORDM will be included in the disclosure.

3.7 Cross-border activities

Disclosure of ToV is made pursuant to the national code of the country where the HCP or ORDM principally practices or where the HCO has its principal place of operation, whether the ToV occurs in or outside of that country.

If an HCP or ORDM changes their principal country of practice, then their ToV data will be disclosed for where the HCP or ORDM has their principal place of operation as at the time of disclosure.

4. Specific considerations

4.1 Self-incorporated HCP/ORDM

Eisai's general principle is that where an HCP or ORDM is the sole owner of their own company and Eisai have made a ToV to that company, Eisai will disclose against the individual HCP or ORDM.

4.2 Multi-year agreements

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

5. Disclosure management

Eisai relies upon the lawful basis of pursuing its legitimate interests to disclose any ToV made to an HCP or ORDM pursuant to that engagement. These legitimate interests are:

- i. to comply with Eisai's obligations under the ABPI Code; and more generally
- ii. to help increase transparency in the interactions between pharmaceutical companies and HCPs and ORDMs and build and maintain confidence in these interactions; and reduce the perception of conflicts of interest in such interactions.

Eisai's legitimate interests must be balanced against the interests and rights of HCPs and ORDMs. Eisai considers this balance is met by informing the HCPs and ORDMs about how and why their data will be used for ToV disclosure purposes and taking account of how they may reasonably expect their data to be used. In addition, HCPs or ORDMs have the right to object to the disclosure of ToV. To exercise this right, HCPs or ORDMs must follow instructions within section 5.2.

Where an HCP or ORDM has not objected (or has objected, but Eisai has not accepted the objection) to the disclosure of their ToV, Eisai will disclose any ToV on an individual basis.

Where an HCP or ORDM has objected and Eisai has accepted their objection to the disclosure of their ToV, Eisai will disclose any ToV on an aggregate basis.

5.1 Lawful basis for disclosure of ToV

Eisai will disclose any ToV upon the lawful basis of pursuing its legitimate interests.

Eisai can disclose all applicable HCO ToV without the need for a lawful basis under data protection laws where these disclosures will not involve personal data.

Where an HCP or ORDM is engaged in multiple activities throughout the disclosure year and an HCP or ORDM has objected (and Eisai has accepted the objection) to any one of these activities, Eisai will disclose the total ToV for that year in aggregate form.

5.2 Management of disclosure queries

Where an HCP or ORDM wishes to object or later wishes to retract a previous objection to the disclosure of their ToV, this request should be made directly via the ABPI Disclosure Portal in the first instance or to the UK & ROI Disclosure Reporting Lead either by email to Eisai_UK_ROI_disclosure@eisai.net or by post to:

UK & ROI Disclosure Reporting Lead
EMEA Medical Compliance Department
Eisai Limited
European Knowledge Centre
Mosquito Way
Hatfield, AL10 9SN

Where a request is received by email or post, Eisai will raise the query via the ABPI Disclosure Portal on the HCP or ORDM's behalf.

When a request to retract an objection is made, the ToV (and any others made to the HCP or ORDM in that disclosure year) will be published on the ABPI disclosure database as soon as possible.

When an objection to disclosure is made, the request will be reviewed, and if accepted, the ToV (and any other ToV made to the HCP or ORDM in that disclosure year) will be added to the aggregated value, which is Eisai's lump sum of HCP/ORDM ToV disclosures which have been anonymised as soon as possible.

Where the objection is not accepted, the HCP or ORDM will be notified and the ToV will be disclosed against the HCP or ORDM.

6. Disclosure Form

Eisai uses the centralised ABPI platform for UK disclosure.

Eisai's data will be published on 28th June 2024.

7. Financial data

7.1 Currency

Disclosure is made in the local currency. Foreign exchange rates are based on published commercial rates used internally by Eisai.

Exchange rates are applied to ToV, including R&D ToV, using a yearly average exchange rate.

7.2 VAT

ToV are disclosed using gross values.

An exception to this is R&D ToV which are reported gross or net depending on how the data is captured and reported in third party payment systems.

7.3 Calculation rules

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

