



UNITED KINGDOM

METHODOLOGICAL NOTE

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

(Information for Reporting of 2021 Data)

1. Introduction

EFPIA has stated that “Collaboration between pharmaceutical industry and Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) benefits patients. It is a relationship that has delivered numerous innovative medicines and changed the way many diseases impact on our lives.

Bringing greater transparency to this already well-regulated and vital relationship, builds understanding of HCPs/HCOs collaboration and, in the context of increasing societal expectations on transparency, addresses directly public concerns about interactions between the medical community and the pharmaceutical industry”.

¹ (EFPIA).

Eisai Limited (hereinafter referred to as “Eisai”) is committed to meeting these obligations.

This note describes the methods used by Eisai to meet the obligations for disclosing Transfers of Value (ToV) made to HCPs, Other Relevant Decision Makers (ORDMs) and HCOs under the EFPIA HCP/HCO Disclosure Code and as reflected in the ABPI Code of Practice. This note includes a general summary and any country specific considerations.

2. Definitions

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

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

The term **Other Relevant Decision Makers** 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 are not HCPs.

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 EFPIA and the ABPI Code, 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 Values

Where Eisai does not have consent to disclose a ToV or Eisai receives an objection to disclose a ToV, the ToV will be aggregated. Aggregated ToVs are ToVs 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 anonymized.

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.

ToV made to a group of HCPs and/or ORDMs, such as group transportation e.g., bus chartering to an event.

All R&D ToVs are aggregated as a single value. The ToVs 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

ToV can be made to the HCP, ORDM or HCO directly, (for e.g., payment to an HCP for giving expert advice in an Advisory Board or providing any other service that would be considered a 'fee for service' interaction).

3.5 Indirect ToV or Benefit in Kind (BIK)

ToV can be made to the HCP, ORDM or HCO indirectly i.e., through any third party working on behalf of Eisai or as BIK.

An example of an indirect ToV would be a payment that is made to an HCO by Eisai in respect of activities undertaken by an HCP, where either the HCP requests the payment is made to the HCO or the payment is pursuant to a contract between Eisai and that HCO.

An example of a BIK payment would be registration fees paid by Eisai to a conference provider in respect of an HCP's registration fee for that conference.

Where an individual HCP or ORDM recipient of any ToV or BIK made by a third party (on behalf of Eisai) is known to Eisai and consent to disclose has been obtained from that recipient or no objection to disclose has been made by the recipient, any such ToV will be disclosed against the individual HCP or ORDM. In any other circumstances, or where a recipient has objected to the disclosure of any such ToV, Eisai will disclose on an aggregate basis.

Eisai will make every effort to disclose against individual HCPs or ORDMs where it is known that they have undertaken activities on behalf of an HCO and where the HCO has been paid for this service.

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 fee for service/ BIK, the ToV is not included in the disclosure.

In the case of partial attendance, any ToV received by an HCP or ORDM as funding, fee for service, or BIK 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 date.

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.

Consent to disclosure of any ToV has been sought on an event-by-event basis.

Where an HCP or ORDM has not objected to the disclosure of their ToV, Eisai will disclose any ToV on an individual basis. Where an HCP or ORDM has indicated that they do not consent to disclose or have objected to the disclosure of their ToV, Eisai will disclose any ToV on an aggregate basis.

Eisai will make every effort to understand an individual's HCP or ORDM's position on consent if it is not known. If we are unable to ascertain consent, we will disclose any ToV on an aggregate basis.

5.1 Legal basis for transfer of ToV

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

Consent to disclosure of ToVs has been sought on an event-by-event basis. Where consent has not been provided, Eisai will make every effort to ascertain the HCP or ORDM's position on consent.

Eisai is not required to obtain consent from HCOs and will disclose all applicable HCO

ToVs.

Where an HCP or ORDM is engaged in multiple activities throughout the disclosure year and Eisai have been either unable to obtain consent for all activities or the HCP or ORDM has objected to any one of these activities, Eisai will disclose the total ToV in aggregate form.

5.2 Management of disclosure queries

Where an HCP or ORDM wishes to change their consent to disclose or objects 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

Eisai will raise the query via the ABPI Disclosure Portal on an HCP or ORDM's behalf.

Where a request to change consent is received, Eisai will process this as soon as possible. Where the request is to withdraw consent, the ToV (and any other ToVs 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 anonymized as soon as possible.

When an objection to disclosure is made, the ToV will be added to the aggregated value, which is Eisai's lump sum of HCP/ORDM ToV disclosures which have been anonymized as soon as possible.

6. Disclosure Form

Eisai uses a centralised ABPI platform for UK disclosure.

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 included or excluded

ToVs 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.

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<https://efpia.eu/relationships-codes/the-efpia-disclosure/>

