



ITALY

METHODOLOGICAL NOTE

on disclosure of transfers of value to healthcare professionals and organizations

(Information is stated as of 21 June 2023)

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 Organizations (HCOs). This note includes a general summary and any country specific considerations.

Definitions

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

Disclosure’s scope

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

Period of publication of the ToV

For the purposes of publication, Eisai considers the date on which the payment was made to the HCP or to the health organization.

ToV in direct form

The ToV can take place directly, e.g., paying a healthcare professional for advice on an Advisory Board.

ToV in indirect form

The ToV can take place indirectly, e.g., sponsorship through providers of doctors at conferences and congresses with the payment of the registration fee or travel and hospitality expenses.

In the case of indirect financing, if the ToV (net of agency fees) is known and the consent to the publication of the health worker has been obtained, this will be done individually. Otherwise, the communication will be made in aggregate form.

ToV in case of partial participation or cancellation

In case of cancellation, the ToV will not be published as no value has been transferred. In case of partial participation, the ToV will be published.

Collection of consents

For the Transfers of Value to Healthcare Professionals published on an individual basis, Eisai proceeds to acquire in advance, activity by activity - for each stipulated contract -, the consent to the publication of personal data by the interested parties in accordance with the provisions of the applicable legislation on protection of personal data.

If the Healthcare Operator has denied consent at least once during the year, all related TOS will be published in aggregate form.

The ToV relating to contracts where consent to individual publication is lacking will also be published in aggregate form.

The aggregate shows the number of operators who refused consent and the total amount.

Form of disclosure

The publication is made on the Eisai website in the relevant country.

Multi-year contracts

For payments made under multi-year contracts, the actual payment date will be considered valid.

Multiple agreements with health organizations

Eisai publishes the amount paid to the health organization established as a supplier in its financial system.

Research and Development:

All ToV conducted by Eisai relating to the management of clinical trials, non-clinical studies, and non-interventional studies, are communicated on an aggregate basis.

ToVs excluded

Eisai acknowledged that some ToVs are not subject to publication, as per the EFPIA code or local pharmaceutical ethical codes.

- ToVs made by another company in the context of a co-promotion agreement with Eisai, will be communicated by the other company.
- ToVs recognized as part of a market research study in which Eisai does not know the identity of the participating healthcare operators or organizations, will be published on an aggregate basis if the data is available.
- costs related to events, such as the rental of equipment associated with one-off events, room reservation, rental of video projector and audiovisual equipment.
- ToVs made to a group of health professionals, such as group transport (hiring a bus for an event), will be published on an aggregate basis, if the data is available.

Activities abroad

The publication of the ToV must be carried out in accordance with the code of the country in which the healthcare worker has his residence, or where the healthcare organization has its registered office, whether the ToV occurs internally or externally. of that country.

If a healthcare professional changes their residence, the information will be disclosed at the place of residence at the time of publication.

Disclosure financial data

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 commercial or promotional TOV based on an average rate for the disclosure period.

VAT included or excluded

ToV are disclosed VAT excluded, withholding tax included.

Calculation rules

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

