Microlearning deck

EFPIA Code of Practice

CHAPTER 5

Disclosure of Transfers of Value

What, Why, How to comply with Disclosure of Transfers of Value

WHAT (definition)

What is Disclosure?

Disclosure is the publication by EFPIA member companies of transfers of value provided to Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs).

EFPIA Member Companies also disclose support provided to Patients Organisations (POs).

What must be disclosed?

Transfers of value include:

- Donations & grants,
- Sponsorship agreements including registration fees and travel and accommodation,
- Fees for services (speaking, consulting, advisory boards),
- Research & Development payments.

WHY (rationale)

Why does disclosure matter?

Collaboration between pharmaceutical industry and HCPs, HCOs and POs contributes to better outcomes for patients. These partnerships have led to major advances in healthcare by helping to prevent disease, improve diagnosis, and develop innovative treatment options.

While the relationships are already governed by strict rules, transparency further strengthens public confidence and demonstrates the value that such collaborations bring to patients and society.

Transparency builds public trust by enabling patients, payers and regulators to assess whether financial relationships between industry and healthcare professionals could influence prescribing or clinical decisions.

Who benefits from disclosure?

Patients, healthcare community, regulators and the public all benefit from disclosure through greater transparency and a better understanding of how industry collaborations support medical research, education and patient care.

At the same time, disclosure benefits the pharmaceutical industry by demonstrating its commitment to transparency, accountability and ethical engagement.

HOW (Key rules to follow)

Who must disclose

All EFPIA members, and companies that are members of national trade associations represented within EFPIA, even if they are not direct EFPIA members. This includes most major pharmaceutical companies operating across Europe.

What is the deadline?

Disclosure must be published within 6 months after the end of the reporting year (i.e. by 30 June each year) and remain publicly available for 3 years.

Individual data

As per the GDPR, named disclosure of HCPs requires a legal basis to name an HCP – either individual consent or legitimate interest. Companies must have a documented process.

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Disclosure
Real life scenarios

Q1: A pharma company pays an HCP's fee to attend an international advisory board. Does this need to be disclosed?

A: Yes, all fees for services paid to HCPs — including advisory board participation, travel, and accommodation — are transfers of value and must be disclosed individually (by name, with the HCP's consent) or in aggregate if consent is not obtained and another legal basis (e.g. legitimate interest) not used.

Q2: A pharma company provides an unrestricted educational grant to a medical society. Must this be disclosed?

A: Yes, grants and donations to HCOs and POs must be disclosed. The company should record the name of the organisation, the purpose of the grant, and the monetary value — even when the grant is unrestricted and no product is mentioned.

Q3: An HCP refuses to give consent for named disclosure. Can the pharma company still pay them a consulting fee?

A: Yes, but aggregate disclosure applies. The company may still engage and compensate the HCP. However, the transfer of value must be captured in the aggregate (non-named) total for the reporting year. The HCP's lack of consent must be documented in the company's records. Alternatively, the company may use an alternative legal basis to disclose, e.g. legitimate interest which does not require consent. If this legal basis is to be used, the HCP must be informed prior to engaging with them.

Q4: A pharma company sponsors a third-party event, and the third party is responsible for indicating the particular HCPs by name who will be invited, should the indirect ToV to these HCPs be disclosed?

A: Yes. If the third party uses some of the received sponsorship to invite HCPs that they select or to hire HCPs as speakers for that congress and the pharma company does not know the names of the HCPs, the ToV must be disclosed under the category 'Sponsorship' naming the recipient HCO if the third party is an HCO or a non HCO third party acting on the HCO behalf.

If the sponsorship contract requires the third party to use some of the sponsorship funding to invite a given list of HCPs to that congress (e.g., fund their registration), this should be disclosed individually under the name of each HCP.

Q5: Does the system cover all payments to healthcare professionals at an individual level?

A: No. Payments made for research and development activities are disclosed in aggregate. For the purposes of the disclosure, these activities are defined as transfers of value to HCPs or HCOs related to the planning or conduct of:
- non-clinical studies (as defined in OECD Principles on Good Laboratory Practice);
- 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.

Meals and drinks are not disclosed, but a threshold has been applied in each country, limiting hospitality under a certain value. As well as inexpensive items of medical value; information and educational materials designed for patients; samples; and activities solely relating to over the-counter medicines.

Q6: How should disclosure be managed where the Recipient gives consent for travel & accommodation costs related to a consultancy to be disclosed but does not consent for the consultancy fees to be disclosed?

A: A pharma company must not allow 'cherry picking' of what ToVs to disclose by a recipient as this has the potential to mislead on the scale or nature of the interaction(s).

If a Recipient gives only partial consent to any aspect of disclosure e.g., the recipient does not allow disclosure of all categories or of all ToVs, all ToVs made to that Recipient should be disclosed in the aggregate category, subject to applicable laws.

Curious to know more about Disclosure?

Please refer to following link or connect with your Ethics and Compliance Officer:

Chapter 5 (articles 22 to 24), pages 28-31
Annex A – Standardised disclosure template
Annex B – EFPIA guidance
Annex 1 - Recommendation

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