

Guidance on the Methodological Note for Annual Disclosure of Transfers of Value to Health Professionals, Other Relevant Decision Makers and Healthcare Organisations

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Key message

Due to the ABPI's obligation to comply with EFPIA requirements, all HCP/HCO methodological notes must now comply with a new standardised structure.

The new structure must be used for 2025 transfers of value, reported in 2026, and beyond.

The PMCPA has produced an optional HCP/HCO methodological note template to help companies meet the mandatory structure requirements.

The template is labelled as 'optional' because companies can choose to create their own document if they wish. However, companies must use the same headings and subheadings as in the template. If something is not applicable to a particular company, it must still include the heading/subheading in their methodological note and state 'not applicable'.

Introduction

The pharmaceutical industry's relationships with health professionals (HCPs), other relevant decision makers (ORDMs) and healthcare organisations (HCOs) is a key area of public interest. Members of the public want to be confident that such relationships are appropriate and that they can trust their health professional to provide high quality care based on clinical evidence and experience. There are detailed requirements in the ABPI Code of Practice for the Pharmaceutical Industry setting out the basis of these relationships which include disclosure obligations. Since 2012, certain transfers of value have been required to be collected and disclosed. Current ABPI Code requirements mean that data identifying HCPs, ORDMs and HCOs, who have received certain transfers of value, are published on a publicly available central platform, Disclosure UK. The platform was launched in June 2016, when 2015 data was published, and currently lists data for the last three calendar years.

By creating greater transparency around the pharmaceutical industry's collaborations and partnerships with HCPs, ORDMs and HCOs, the ABPI Code requirements for disclosure of certain transfers of value aim to improve understanding and increase the public's confidence in these relationships.

The ABPI Code disclosure requirements are predominantly set out in Clauses 28 to 31 of the 2024 Code.



<u>Methodological Note for Annual Disclosure of Transfers of Value to Health Professionals, Other Relevant Decision Makers and Healthcare Organisations.</u>

As part of the requirements of the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations, which has been transposed in the ABPI Code, each company is required, at the same time as it discloses the data, to publish a methodological note. This document is also submitted to and published via Disclosure UK and gives important additional information about, and context to, the disclosed data. Clause 28.6 of the ABPI Code states:

'Each company providing transfers of value must publish a note summarising the methodologies used by it in preparing the disclosures and identifying each category of transfer of value. The note, including a general summary and/or country specific considerations, must describe the recognition methodologies applied and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues relating to the timing and amount of transfers of value for the purposes of this Code.'

Following an update to the EFPIA Code Annex B in 2025, Member Companies, and companies that are members of Member Associations, must now implement a unified format and publication standard, which requires that:

- All methodological notes must comply with a new standardised structure
- The new structure must be used for 2025 transfers of value, reported in 2026, and beyond

Whilst the above requirements for a standardised methodological note structure are mandatory in the EFPIA Code, they are not included in the current 2024 ABPI Code. However, all ABPI member companies and non-member companies who have formally agreed to abide by the ABPI Code and accept the jurisdiction of the PMCPA, are required to submit their methodological notes for 2025 transfers of value (reported in 2026) in the standardised format as stipulated by EFPIA.

Whilst companies will not be found in breach of the 2024 ABPI Code for not complying with the new EFPIA methodological note structure requirements, the PMCPA may proactively monitor companies for compliance with the new structure for transfers of value made in 2025 that are disclosed in 2026, and thereafter, until a new edition of the ABPI Code is published.

The PMCPA has produced an **optional methodological note template**, available under <u>Publications</u> on the PMCPA website, which can be downloaded and used by companies to help meet the new structure requirements.

The new standardised methodological note format is outlined below. In line with EFPIA requirements, the order of the content **must not deviate from the structure laid out below**. Where a sub-section is not relevant, companies must still include the section in their methodological note and state 'not applicable'.

UK specific considerations to assist in completing the template are labelled as 'UK variation'.



EFPIA MANDATED HEADINGS AND SUB-HEADINGS	CONSIDERATIONS TO ASSIST COMPLETION OF TEMPLATE
1. Definitions	
1.1. Recipients	Include types of recipients and define e.g. health professionals
	How are ToVs to retired health professionals or other relevant decision makers managed?
	How is data relating to deceased health professionals or other relevant decision makers managed? See also, PMCPA Q&A - How should companies publish data about deceased health professionals?.
1.2. Kind of ToVs	Define the different kinds of ToVs (e.g. donations and grants, collaborative working (<i>UK variation</i>), contribution to costs of events, contracted service fees and expenses, R&D etc.)
2. Disclosure's Scope	
2.1. Products concerned	Which product classifications are included in the disclosure (e.g. Prescription Only Medicines)? State whether over-the-counter medicines or medical device transfers of value are included or partially included.
2.2. Company concerned	 Is it clear whether the disclosures cover company subsidiaries, affiliates, etc.? Or, have these been disclosed separately? If the company has changed name or merged etc., how is this explained? Can relevant disclosures be easily tracked? Consider adding information to any previous year's methodological note to ensure a member of the public can identify related disclosures.



	2.3.	Excluded ToVs	b	Are there any types of ToV which have been excluded from the disclosure see Clause 1.25)?
	2.4.	ToVs date		Vhat date period is covered by the lisclosure?
	2.5.	Direct ToVs	re	Catagorise the types of activities esulting in direct transfers of value e.g. fee for service)
	2.6.	Indirect ToVs	re	Categorise the types of activities esulting in indirect transfers of value e.g. via a third-party event organiser)
	2.7.	Non-monetary ToVs	re	Catagorise the types of activities esulting in non-monetary transfers of value (e.g. staff time)
	2.8.	ToVs in case of partial attendances or cancellation and refund	а	How have ToVs in case of partial attendances or cancellation and efund been managed?
	2.9.	Cross-border activities		How have ToVs related to cross- corder activities been managed?
	2.10.	R&D	ir F O	Summarise the types of activities not definition in the ABPI Code; have other R&D activities been included in the disclosure where appropriate?
	2.11.	Voluntary disclosure	i. is	Are "voluntary disclosures" included e. do the disclosures go beyond what is required by the ABPI Code? If so, explain.
3.	Speci	fic considerations		
	3.1.	Country unique identifier		Are country unique identifiers ncluded?
	3.2.	Self-incorporated HCP	T 0	What approach is taken to disclose ToVs to health professionals with their own Limited company? (Clauses 1.8 and 1.25 should be consulted.)



3	3.3.	Multi-year agreements	•	How have ToVs made under multi- year agreements been handled?
3	3.4.	Country specificities	•	UK variation: When working with other pharmaceutical companies, how are disclosures handled? How are transfers of value divided amongst the parties (e.g., collaborative working projects, etc.)?
			•	UK variation: Where are the links to the collaborative working executive summaries (see NOTE G of Mandatory HCP/ORDM/HCO disclosure template). Are the necessary links included and active?
3	3.5.	Quality Checks	•	Summary of internal company pre- disclosure quality checks undertaken prior to data submission – were these completed, and how?
4. D	ata p	protection legal basis		
	1.1.	Consent collection	•	Which lawful basis has been used to publish individual HCP/ORDM information? E.g. Consent or Legitimate Interests (if the latter move straight to 4.2).
			•	Are the appropriate arrangements in place to lawfully disclose the information and are recipients aware of the process?
			•	Partial disclosures - how many individuals agreed to some payments being disclosed individually, and some in aggregate? The supplementary information to Clause 28.5 should be consulted.
			•	How is withdrawal of consent managed
4	1.2.	Legitimate interests	•	Are the appropriate arrangements in place to lawfully disclose the information and are recipients aware of the process?



			•	Provide details of the balancing test, right to object etc. How are objections to publication under Legitimate Interests managed?
5.	Form	of disclosure		
	5.1.	Date of publication	•	State as DD/MM/YY
	5.2.	Disclosure platform	•	State 'Disclosure UK – www.disclosureuk.org.uk'
	5.3.	Disclosure language	•	State 'English'
6.	Discl	osure financial data		
	6.1.	Currency	•	State 'GBP' How has the company treated currency aspects (specify the exchange rate)?
	6.2.	VAT included or excluded	•	Has VAT been included or not? Any other tax considerations (<i>UK variation</i>)?
	6.3.	Calculation rules	•	What calculation rules have been used (e.g. in-kind ToVs, other non-monetary values)
7.	Addit	ional Information	•	Include as necessary