



## PMCPA Guidance for Disclosure of Transfers of Value to Patient Organisations and Members of the Public

This PMCPA Guidance provides an overview of the annual disclosure requirements to publish certain transfers of value to patient organisations and members of the UK public including patients and journalists set out in Clauses 29, 30 and 31 of the 2021 ABPI Code of Practice and their supplementary information and provides guidance to support companies to fulfil these requirements.

The PMCPA cannot approve any materials or activities, it can only give informal advice based on its interpretation of the ABPI Code. In the event of a complaint being received about a matter upon which advice was sought, it would be considered in the usual way; the ABPI Code of Practice Appeal Board would make the final decision if a case went to appeal.

Annual Disclosure requirements were updated in the 2021 Code to include an additional requirement to disclose in aggregate payments to members of the UK public not representing a patient organisation, including patients and journalists who provide certain contracted services. These services include speaking at meetings, assistance with training, writing articles and/or publications, participating in advisory boards, advising on the design etc. of clinical trials and participating in market research where such participation involves remuneration and/or travel. This was agreed by the ABPI Board and is part of its disclosure journey. Further, it aligns to the spirit of the EFPIA guidance [‘Working together with patients – Principles for remunerating patients, patient organisation representatives and carers for work undertaken with the pharmaceutical industry’](#).

An optional template (**Figure 1A**) was developed and published<sup>1</sup> which companies can use to fulfil the obligation to disclose payments to patient organisations and members of the public, including patients and journalists. The optional template can be amended as companies wish to support their disclosures (example in **Figure 1B**). Companies can publish the data in an alternative manner ensuring the publication meets the Code requirements. An example of how the optional template might be completed is given in **Figure 3** below. A methodological note which summarises the methods used by a company in preparing these disclosures must be included with the publication.

The disclosure of transfers of value to members of the public including patients and journalists applies to those made in 2022 and each calendar year thereafter.

# Optional Disclosure Template

The optional template(s) can be downloaded from the PMCPA website - PMCPA Publications<sup>1</sup>

Optional Disclosure Template for Patient Organisations and the Public including Patients and Journalists										
Companies must include a note of methodologies used in preparing the disclosures										
Types of the Support or Services Provided										
Patient Organisation Name	Country	Financial Support			Non-financial Support	Contracted Services (Fees and expenses should be disclosed separately)		Non-monetary Benefit for PO <sup>2</sup>	Optional Indication of Patient Organisation's Total Income and/or the Company's Support as a Percentage	Description of Services
		Grants add a line for each Grant	Sponsorship of Meetings add a line for each sponsorship	Other Sponsorships add a line for each sponsorship	Donations add a line for each donation	Fees	Out of pocket/ expenses			
Patient Organisation (add additional table for each Patient Organisation)										
Members of the Public	Description of Services <sup>1</sup>	Add additional lines as required			N/A	N/A	N/A	N/A		
	Description of Services <sup>1</sup>	Add additional lines as required			N/A	N/A	N/A	N/A		
	Aggregate amount attributable to transfers of value to such Recipients							N/A	N/A	N/A
	Number of Recipients in aggregate disclosure							N/A	N/A	N/A
Patients	Description of Services <sup>1</sup>	Add additional lines as required			N/A	N/A	N/A	N/A		
	Description of Services <sup>1</sup>	Add additional lines as required			N/A	N/A	N/A	N/A		
	Aggregate amount attributable to transfers of value to such Recipients							N/A	N/A	N/A
	Number of Recipients in aggregate disclosure							N/A	N/A	N/A
Journalists	Description of Services <sup>1</sup>	Add additional lines as required			N/A	N/A	N/A	N/A		
	Description of Services <sup>1</sup>	Add additional lines as required			N/A	N/A	N/A	N/A		
	Aggregate amount attributable to transfers of value to such Recipients							N/A	N/A	N/A
	Number of Recipients in aggregate disclosure							N/A	N/A	N/A

1. Add a clear description which is sufficiently complete to enable the reader to understand the nature of each support or services provided

2. For example, employee hours or company's facilities offered to support a Patient Organisation activity

Figure 1A. default optional template format

<sup>1</sup> PMCPA publications - <https://www.pmcpa.org.uk/about-us/publications/>

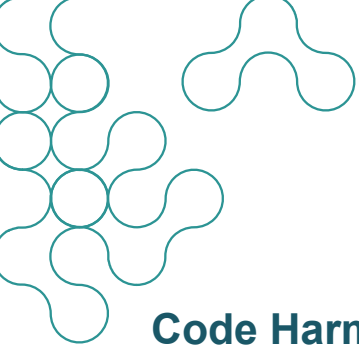
## Optional Disclosure Template for Patient Organisations and the Public including Patients and Journalists

Companies must include a note of methodologies used in preparing the disclosures										
Patient Organisation Name	Country	Types of the Support or Services Provided						Non-monetary Benefit for PO <sup>2</sup>	Optional Indication of Patient Organisation's Total Income and/or the Company's Support as a Percentage	Description of Services
		Financial Support			Non-financial Support	Contracted Services				
Grants <small>add a line for each Grant</small>	Sponsorship of Events/ Meetings <small>add a line for each Sponsorship</small>	Other Sponsorships <small>add a line for each sponsorship</small>	Donations <small>add a line for each donation</small>	Fees	Out of Pocket Expenses/Other Expenses					
Patient Organisation <small>(add additional table for each Patient Organisation)</small>										
Patient Organisation <small>(add additional table for each Patient Organisation)</small>										
Patient Organisation <small>(add additional table for each Patient Organisation)</small>										
<b>The Public, including Patients and Journalists</b>						Contracted Services <small>(Fees and expenses should be disclosed separately)</small>		Description of Services		
						Fees	Out of Pocket Expenses/Other Expenses			
<b>Members of the Public</b>	Description of Services <sup>1</sup>			<i>Add additional lines as required</i>		N/A	N/A			
	Description of Services <sup>1</sup>			<i>Add additional lines as required</i>		N/A	N/A			
	Aggregate amount attributable to transfers of value to such Recipients			Number of Recipients in aggregate disclosure				N/A		N/A
<b>Patients</b>	Description of Services <sup>1</sup>			<i>Add additional lines as required</i>		N/A	N/A			
	Description of Services <sup>1</sup>			<i>Add additional lines as required</i>		N/A	N/A			
	Description of Services <sup>1</sup>			<i>Add additional lines as required</i>		N/A	N/A			
Aggregate amount attributable to transfers of value to such Recipients			Number of Recipients in aggregate disclosure				N/A		N/A	
<b>Journalists</b>	Description of Services <sup>1</sup>			<i>Add additional lines as required</i>		N/A	N/A			
	Description of Services <sup>1</sup>			<i>Add additional lines as required</i>		N/A	N/A			
	Aggregate amount attributable to transfers of value to such Recipients			Number of Recipients in aggregate disclosure				N/A		N/A

<sup>1</sup> Add a clear description which is sufficiently complete to enable the reader to understand the nature of each support or services provided  
<sup>2</sup> For example, employee hours or company's facilities offered to support a Patient Organisation activity

**Figure 1B.** example of amended optional template format

<sup>1</sup> PMCPA publications - <https://www.pmcpa.org.uk/about-us/publications/>



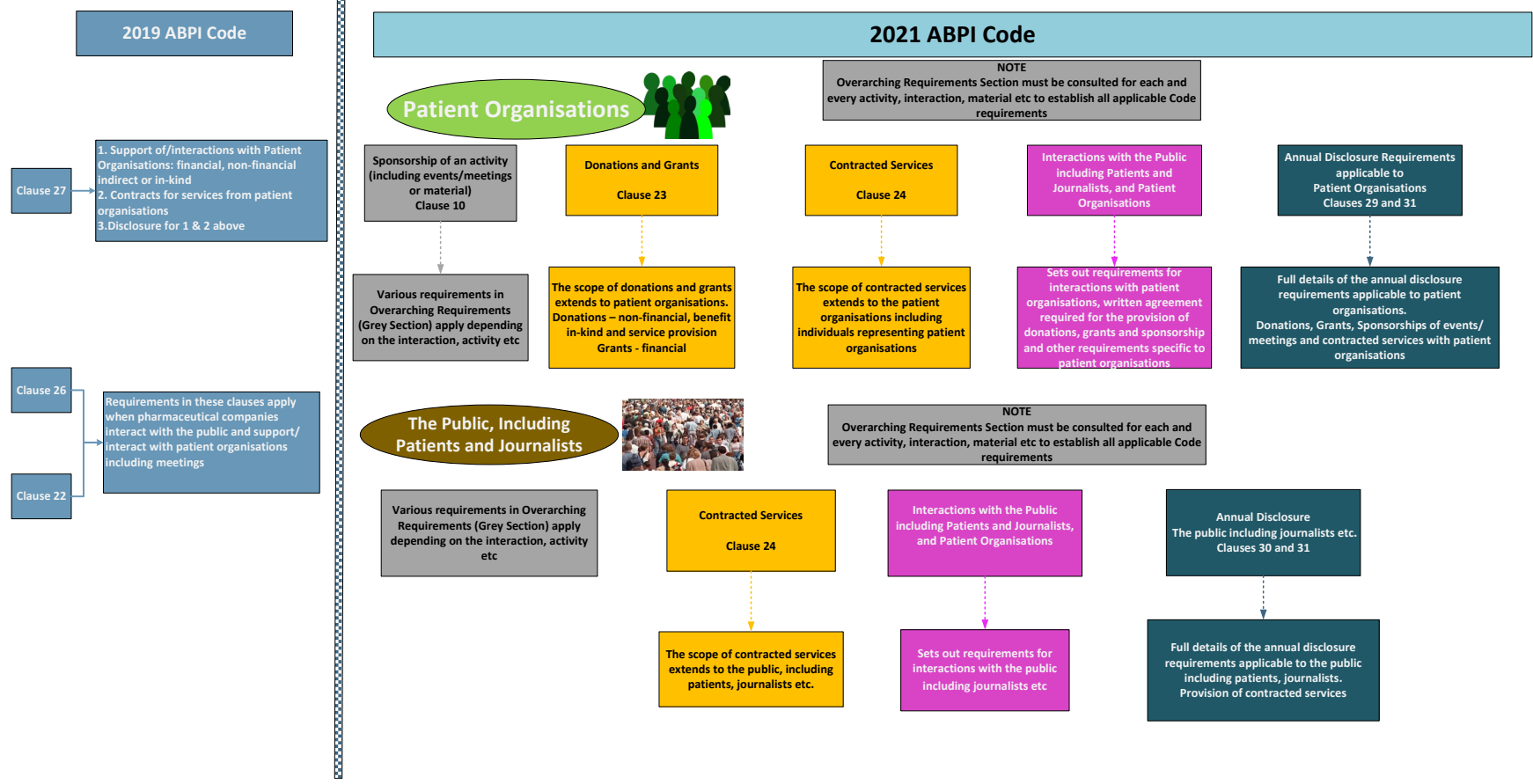
## Code Harmonisation

The 2021 ABPI Code implemented, among other things, the harmonisation of the EFPIA Codes, now the EFPIA Code of Practice, 2019. Patient organisations and individuals representing patient organisations were incorporated in many areas of the Code such as donations and grants, sponsorship (including events/meetings) which previously only referred to health professionals, other relevant decision makers, healthcare organisations etc. (**Figure 2** below).

Similarly, health professionals, other relevant decision makers and healthcare organisations were incorporated into areas of the Code which previously only referred to patient organisations such as the requirements that no company may require that it be the sole funder or sponsor of a healthcare organisation or patient organisation or any of its programmes and that a company must not make public use of a healthcare organisation or patient organisation's logo and/or proprietary material without the organisation's written agreement. Members of the public, including patients and journalists were also included in the requirements for contracted services.

# Interactions with Patient Organisations and Members of the Public Including Patients and Journalists, 2019 ABPI Code compared with the 2021 ABPI Code

This information has been developed to provide a high level overview to support individuals understanding of aspects of the 2021 ABPI Code of Practice  
 Definitions in the 2021 Code must be read in conjunction with this graphic. No reproduction or copy without permission



**Figure 2.** Interactions with Patient Organisations and Members of the Public Including Patients and Journalists – 2019 Code versus 2021 Code



## Patient Organisations

### Annual Disclosure of Contracted Services, Donations, Grants and Sponsorship (including in relation to events/meetings) Provided to Patient Organisations

The organisations or individuals which are captured by these requirements are set out in Clauses 1.15 and 1.16 of the 2021 Code. Clause 1.15 defines a 'Patient organisation' as an organisation mainly comprising of patients and/or caregivers or any user organisation such as a disability organisation, carer or relative organisation and consumer organisation that represents and/or supports the needs of patients and/or caregivers and Clause 1.16 defines 'Individuals representing patient organisations' as a person who is mandated to represent and express the views of a patient organisation.

Clauses 29 and 31 set out the overarching requirements for the annual disclosure of certain transfers of value to patient organisations. Clauses 10, 23, and 24 may provide additional information which could be helpful with these disclosures.

The Code requires disclosure of donations, grants and sponsorship to patient organisations and when contracting with patient organisations or individuals representing patient organisations to provide services for companies. These disclosures should be published annually in the first 6 months after the end of the calendar year in which the transfers of value/ payments were made e.g., published by end of June 2023 for applicable transfers of value in 2022.

**Figure 3** illustrates an example of how the optional template may be completed for disclosure of transfers of value to Patient Organisations.

Optional Disclosure Template for Patient Organisations and the Public including Patients and Journalists											
Companies must include a note of methodologies used in preparing the disclosures											
Annotated 221011											
	Patient Organisation Name	Country	Types of the Support or Services Provided						Non-monetary Benefit for PO <sup>2</sup>	Optional Indication of Patient Organisation's Total Income and/or the Company's Support as a Percentage	Description of Services
			Financial Support			Non-financial Support	Contracted Services (Fees and expenses should be disclosed separately)				
			Grants (Clause 23) add a line for each Grant <i>(The supplementary information to Clause 23.2 states: details of each grant must be publicly disclosed annually, giving in each case the financial amount or value and the name of the recipient institution, organisation or association. Grants are generally the provision of funds as defined in Clause 1.5, where companies have a different definition this should be made clear in the methodological note and this template amended accordingly.)</i>	Sponsorship of Events/ Meetings (Clause 10) add a line for each Sponsorship <i>(Clause 10.11 states: financial details for contributions to costs related to events/meetings (sponsorship) paid to patient organisations or organisations managing an event/meeting on their behalf). Contracts for individuals representing patient organisations to attend events/meetings should be made with and disclosed against the patient organisation.)</i>	Other Sponsorships add a line for each sponsorship <i>(This is the disclosure of sponsorship provision to a patient organisation not related to an event/meeting eg sponsorship for the publication of monthly newsletter. Such sponsorship will have a written agreement in place as set out in Clause 27.2.)</i>	Donations (Clause 23) add a line for each donation <i>(The supplementary information to Clause 23.2 states: details of each donation must be publicly disclosed annually, giving in each case the financial amount or monetary value for each non-financial or indirect support provided. Donations are generally physical items, services or benefits in kind as defined in Clause 1.5, where companies have a different definition this should be made clear in the methodological note and this template amended accordingly.)</i>	Fees	Out of Pocket Expenses/Other Expenses			
Patient Organisation (add additional table for each Patient Organisation)	Patient organisation 1	UK	£500.00							Description of and/or reason for grant	
	Patient organisation 1	FRANCE		£375.00						Information regarding the event/ meeting being supported and the type of support provided should be provided for this example	
	Patient organisation 1	UK	£500.00							Description of and/or reason for grant	
Patient Organisation (add additional table for each Patient Organisation)	Patient organisation 2	UK			£754.00					Information regarding the sponsorship which has been provided eg funding to have an article written on living with a disease	
	Patient organisation 2	GERMANY					£1,500.00	£75.00		Information on the contracted services which have been provided	
Patient Organisation (add additional table for each Patient Organisation)	Patient organisation 3	UK				£600.00			Provision of staff member to input data	0.50%	Clear description of non-monetary donation enabling reader to assess value, e.g. brand new iPad, verses refurbished iPad for patients when receiving infusions
	Patient organisation 3	UK		£150.00							Clear description of the event/ meeting including any expenses which were agreed. (expenses agreed such as travel and accommodation to attend an event/ meeting should not be included in this value as these will be reimbursed at cost and must be evidenced by a valid receipt which should be held on record)
	Patient organisation 4	UK									

Figure 3. example of the optional template filled in for Patient Organisations



## Frequently Asked Questions – Disclosure of Transfers of Value to Patient Organisations

1. **Question** Clause 29.1 supplementary information. This sets out that an indication of the patient organisation's total income and/or the company's support as a percentage of the patient organisation's total income may be given. Also, the optional template for disclosing the patient organisation transfers of value includes a column for this percentage. If it is not mandatory, what is the point of this being in the Code?

**Answer** The publication of the percentage contribution is to encourage greater transparency, aligned with one of the ABPI core principles. Companies are encouraged to be prepared to make available up-to-date information about such activities at any time in response to enquiries. It is understood that it may not be possible for the company to get the relevant information; this would not necessarily be a matter for which a company would be found in breach of the Code.

2. **Question** We used to provide a grant for a staff member of a patient organisation, can we still do so under the 2021 Code?

**Answer** There is no prohibition on a grant being provided to a patient organisation, for example to fund additional operational costs generated by a specific project, providing it meets the requirements of the Code, including the requirements of Clause 23. The principle of not offsetting routine costs of operation should be considered, which applies to Donations and Grants to patient organisations, i.e., that supporting healthcare, research or education does not mean subsidising routine costs of operation. Grants and donations to individuals are prohibited.

3. **Question** If a patient organisation helps with a NICE evaluation, can they be paid for this work?

**Answer** Where a patient organisation provides any service, including for a NICE evaluation, this should be carried out under contracted services as set out in Clause 24, which includes that the remuneration for the services must be reasonable and reflect the Fair Market Value of the services provided. The requirements of Clause 27, in particular Clause 27.5, are also relevant.

4. **Question** Patient organisations often comment on the complexity and length of agreements for grants, donations and sponsorship with pharmaceutical companies. Can these be simplified?





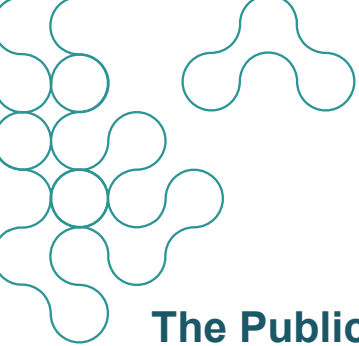
**Answer** The PMCPA encourages companies to do as much as they can to use language that is appropriate for the audience and this principle applies to written agreements. The Code sets out the minimum requirements which must be included in written agreements for grants, donations and sponsorship to patient organisations in Clause 27.2 and Clause 27.5. Company requirements and standard agreements/ templates often go beyond the Code requirements and address other areas.

5. **Question** If a company's global headquarters based in the UK conducts an activity with an EU patient organisation, does this need to be disclosed in the UK?

**Answer** Clause 29.1 states that companies must make publicly available annually, a list of patient organisations to which it provides donations, grants or sponsorship (including in relation to events/meetings) or with whom it has engaged to provide contracted services over the reporting period. This information must be disclosed on the company website either on a national or European level. If disclosing on a national level, the PMCPA's view is that the location where the patient organisation has their principal address (e.g., its registered business address or primary place of operation) should be used to determine in which country the ToV should be disclosed in accordance with the national code of that country, which follows the principle for HCP and HCO disclosure.

6. **Question** Does the methodological note for disclosure to patient organisations need to include whether it includes VAT or not?

**Answer** Companies should make clear in the methodological note for all transfers of value disclosed whether these are inclusive or exclusive of VAT; this includes for patient organisations.



## The Public, including Patients and Journalists

### Annual Disclosure of Contracted Services Provided by the UK Public, Including Patients and Journalists

**Clause 30.1** states that companies must make publicly available annually details of the fees for certain contracted services paid to members of the UK public, including patients and journalists. These services include speaking at meetings, assistance with training, writing articles and/or publications, participating in advisory boards, advising on the design etc of clinical trials and participating in market research where such participation involves remuneration and/or travel.

The disclosure for contracted services provided by members of the public, in accordance with Clause 24, must include:

- the total number of members of the public, including patients and journalists contracted to perform services and the total amount paid per calendar year, and a description of the types of services provided that is sufficiently complete to enable the reader to understand the nature of the services provided without the necessity to divulge confidential information
- companies should provide a breakdown of the total payments to each group of individuals, ie the public, patients and journalists without the necessity to divulge confidential information
- fees and expenses should be disclosed separately.
- Each company must include a note summarising the methodologies used by it in preparing the disclosures and identifying support and services provided.

**Clause 31** states that:

- Disclosures must be made annually in respect of each calendar year and must be in the first six months after the end of the calendar year in which the transfers of value/payments were made.
- The information disclosed must remain in the public domain for at least three years from the time of first disclosure.
- Companies must document all disclosures and retain the records for at least five years after the end of the calendar year to which they relate.

The supplementary information to Clause 31 states that:

- Date of Implementation for Disclosure of Contracted Services Provided by the Public, Including Patients and Journalists - The information required by Clause 30 must be publicly disclosed annually in respect of transfers of value made in 2022 and each calendar year thereafter.

Figure 4 illustrates an example of how the optional template may be completed for disclosure of transfers of value to the Public, including Patients and Journalists.

The Public, including Patients and Journalists		Contracted Services Clause 24 (Fees and expenses should be disclosed separately)		Description of Services	
		Fees	Out of Pocket Expenses/Other Expenses		
Clause 30 sets out the requirements for the Annual Disclosure of Contracted Services Provided by the Public, Including Patients and Journalists, Clause 31 also applies					
Members of the Public	Description of Services <sup>1</sup>	Add additional lines as required		Speaking at internal company meetings	
	Description of Services <sup>1</sup>	Add additional lines as required			
	Aggregate amount attributable to transfers of value to such Recipients (total amount for fees and out of pocket expenses/other expenses. Expenses reimbursed will be those agreed and documented in the agreement/contract signed prior to the contracted service being carried out)		£1,450.00	£42.00	N/A
	Number of Recipients in aggregate disclosure (total number of recipients in the reporting period)		5	3	N/A
Patients	Description of Services <sup>1</sup>	Add additional lines as required		Speaking at internal company meetings	
	Description of Services <sup>1</sup>	Add additional lines as required		Speaking at external meetings	
	Description of Services <sup>1</sup>	Add additional lines as required		Providing advice at Advisory Board meetings for patients	
	Description of Services <sup>1</sup>	Add additional lines as required			
	Aggregate amount attributable to transfers of value to such Recipients (total amount for fees and out of pocket expenses/other expenses. Expenses reimbursed will be those agreed and documented in the agreement/contract signed prior to the contracted service being carried out)		£18,750.00	£2,676.00	N/A
Number of Recipients in aggregate disclosure (total number of recipients in the reporting period)		23	23	N/A	
Journalists	Description of Services <sup>1</sup>	Add additional lines as required		Providing advice at Advisory Board meetings for patients	
	Description of Services <sup>1</sup>	Add additional lines as required			
	Aggregate amount attributable to transfers of value to such Recipients (total amount for fees and out of pocket expenses/other expenses. Expenses reimbursed will be those agreed and documented in the agreement/contract signed prior to the contracted service being carried out)		£23,750.00	£825.00	N/A
	Number of Recipients in aggregate disclosure (total number of recipients in the reporting period)		11	9	N/A

Figure 4. examples of the optional template filled in for the Public including Patients and Journalists



## Frequently Asked Questions - Disclosure of Transfers of Value to the Public, including Patients and Journalists

7. **Question** Please clarify why disclosure of transfers of value to the public, including patients and journalists was added to the 2021 Code?

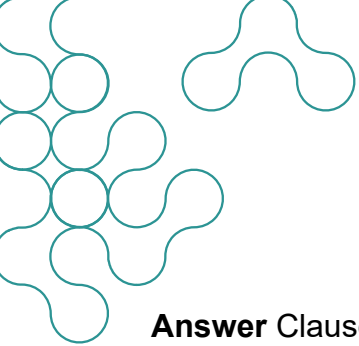
**Answer** This was agreed by the ABPI Board and is part of its disclosure journey. Further, it aligns to the spirit of the EFPIA guidance 'Working together with patients – Principles for remunerating patients, patient organisation representatives and carers for work undertaken with the pharmaceutical industry'

8. **Question** It is challenging to assess Fair Market Value for the public including patients and journalists as these categories are of individuals. Unlike with HCPs, we may not be able to easily access external databases and benchmarking surveys, etc. to develop a Fair Market Value table for such individuals.

**Answer** The PMCPA supports the principles of remuneration that Patients and Patient Organisations should be fairly remunerated for their expertise, contribution, and time. It is important for companies to be able to demonstrate that individuals providing a service get fairly and equitably remunerated for the service being carried out. Fair Market Value is for each company to decide in relation to the service required, taking into consideration the complexity of the task and the individual's expertise. Each company should clearly document its rationale for determining the Fair Market Value.

Companies are advised to refer to the EFPIA document, ['Working together with patients – Principles for remunerating patients, patient organisation representatives and carers for work undertaken with the pharmaceutical industry'](#) when working with Patients and Patient Organisations.

9. **Question** Please provide clarification on payments to members of the public as part of a clinical trial, for example for healthy volunteers, do they fall under the R&D disclosure and would only be part of the 'payments to the public' bucket if the disclosure does not fall within one of the R&D categories set out in Clause 1.20?



**Answer** Clause 30.1 states that companies must make publicly available annually details of the fees for certain contracted services paid to members of the UK public, including patients and journalists. The supplementary information to Clause 24.1 states that only certain services provided by members of the public, including patients and journalists, are covered by the Code; others are clearly outside the scope of the Code. The services covered by the Code generally relate to healthcare, disease or medicine. Providing advice with regard to the design of clinical trials would be an included contracted service whereas being a participant in a clinical trial would not. Participants in clinical trials set out in Clause 1.20 are excluded from Clause 30.

10. **Question** Clause 1.13 states that Other relevant decision maker 'ORDM' particularly includes someone with an NHS role. Would Members of Parliament be seen as ORDMs or members of the public?

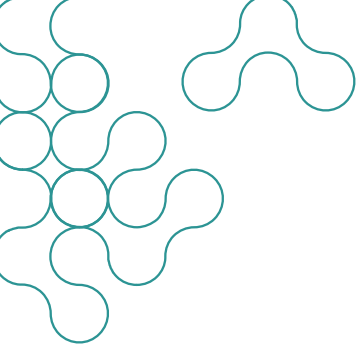
**Answer** ORDMs are not limited to the NHS. In certain circumstances, politicians, policy makers etc might be seen as an ORDM. Much would depend on the activity. This will need to be decided depending on the individual arrangements. MPs have their own rules for disclosing payments and companies would be well advised to mirror such disclosures.

11. **Question** If a patient in another country provides a service to a UK company, should the UK company disclose this? E.g., a French patient provides a service for the UK company, the UK company includes this in their annual disclosure.

**Answer** The Code requires that companies must make publicly available details of the fees for certain contracted services paid to the **UK public**, including patients and journalists. For payments to members of the public based in other countries, it is advisable that relevant advice is sought from the country in which the individual resides.

12. **Question** Where should the methodological note(s) be published for patient organisations and the public including patients and journalists? Should it be incorporated into the methodological note for the disclosure of transfers of value to health professionals, ORDMs and HCOs?

**Answer** Companies could have one methodological note which covers all their disclosure categories; however, it would need to be available on both Disclosure UK and the company website and be clear with regard to what is applicable for each category and the relevant information. Alternatively, companies could have one methodological note for patient organisations/public and another for HCPs/ORDMS/HCOs with the former being on the company website and the latter being on Disclosure UK.



13. **Question** “Fees and expenses should be disclosed separately.” Please clarify what “fees” refers to?

**Answer** Fees would be considered as the remuneration for contracted services whereas expenses would be, for example, travel and accommodation.

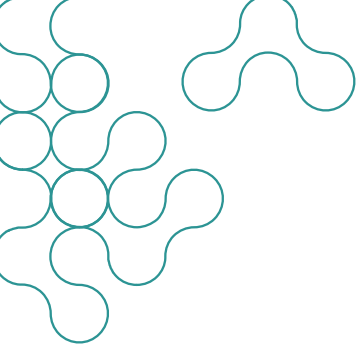
14. **Question** The disclosure of fees for contracted services paid to individuals presumably includes bloggers as they are members of the public.

**Answer** Only certain services provided by members of the public, including patients and journalists, are covered by the Code. The services covered by the Code generally relate to healthcare, disease or medicine. It is important to note that bloggers might be members of the public (patients or journalists) or health professionals and fees for contracted services should be disclosed in line with the relevant Code requirements.

15. **Question** Disclosure for the Public, including patients and journalists is included in the optional disclosure template which also includes Patient Organisations, does this need to be disclosed on the company website and not through the ABPI portal?

**Answer** The Code requires that companies must make publicly available annually details of the fees for certain contracted services paid to members of the UK public, including patients and journalists. It does not require it to be on a specific website (due to the possibility that some companies do not have a UK website). The Code requires that the disclosure of transfers of value to Patient Organisations must be disclosed on the company website either on a national or European level. The disclosure to health professionals, other relevant decision makers and health care organisations is required on the ABPI central platform, Disclosure UK (Clause 28.1 SI refers).

The Disclosure UK platform includes two Disclosure Gateways for the collation of weblinks to patient organisation disclosures and members of the public disclosures on separate company websites. The ABPI asks all disclosing companies to provide a link to their websites with patient organisation disclosures, and/or members of the public disclosures so that the information can be accessible from Disclosure UK. Provision of links is optional, however the ABPI expects all companies signed up to the ABPI Code to work towards providing these links, unless they do not work with patient organisations or members of the public and therefore have no information to provide. Where a link has been provided, following it will navigate to the disclosing company’s website, where their patient organisation



disclosures and/or members of the public disclosures are published. For more information about the Disclosure UK gateways, see [Disclosure Gateway FAQs \(abpi.org.uk\)](https://www.abpi.org.uk/disclosure-gateway-faqs)

END