



Working with patients and patient organisations

A sourcebook for industry

August 2022

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1. Introduction

The ABPI has produced this sourcebook to support pharmaceutical companies, patients and patient organisations work together successfully, with relationships that are in the interests of patients and meet the standards set out in the 2021 ABPI Code of Practice.

The ABPI supports industry and patient organisations working together, with the introduction to the ABPI Code stating:

“Working with patients and patient organisations can bring significant public health benefits.”

There is already a great deal of useful and thoughtful guidance on working together available from national and international organisations, in addition to the ABPI Code. The aim of this sourcebook is to bring together practical tools and tips and to provide pointers to further sources of information, rather than to replicate or replace what already exists.

This sourcebook is designed to help pharmaceutical companies and patient organisations plan how best to engage and work together successfully. Every relationship will be different, and there is no one single template to follow in every situation. We hope that you will find enough advice in the sourcebook to help you work together successfully.

How this sourcebook was developed

In 2018 the ABPI researched how its Code of Practice should be developed to take account of the evolving needs of patients and industry. We talked to compliance, health and business professionals across the pharmaceutical industry as well as representatives of patient organisations. People asked for guidance to sit alongside the ABPI Code, which could help build successful engagement between industry and patient organisations.

We researched what other guidance was available, including with colleagues at the European Federation of Pharmaceutical Industries and Associations (EFPIA), and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

We held workshops which identified and discussed six topic areas where further guidance would be helpful. We have structured the sourcebook around these six areas:

- ◆ Principles and agreements
- ◆ Definitions of participants
- ◆ Events and meetings
- ◆ Research and development
- ◆ Product launches
- ◆ Payment

The first version of the sourcebook became available in 2018. We have now reviewed and updated the sourcebook to reflect the 2021 ABPI Code of Practice and new resources available.



About the ABPI Code of Practice

The ABPI Code is a self-regulatory code, first established by the ABPI in 1958. It is regularly updated and reviewed in a public consultation which includes the Medicines and Healthcare products Regulatory Agency (MHRA), the British Medical Association (BMA), the Royal Pharmaceutical Society (RPS), the Royal College of Nursing (RCN), the Competition and Markets Authority (CMA) and the Serious Fraud Office (SFO).

The ABPI Code demonstrates the commitment of ABPI member companies and companies who have signed up to abide with the ABPI Code to operate in a professional, ethical and transparent manner, to ensure the appropriate marketing of medicines and to support health professionals in the provision of high-quality healthcare, all with the aim of benefiting patients.



The 2021 ABPI Code of Practice sets standards for among other things:

- the promotion of medicines to health professionals and other relevant decision-makers in the UK
- interactions between the industry and health professionals
- the provision of information about prescription-only medicines to the public and patients
- pharmaceutical companies' relationships with patient organisations

The ABPI Code does not cover the promotion of over-the-counter medicines to the public.

ABPI member companies agree to comply with the Code as a condition of membership. In addition, about 120 non-member companies have signed up to its standards. The ABPI Code is administered by the Prescription Medicines Code of Practice Authority (PMCPA), which operates independently of the ABPI.

The ABPI Code incorporates the applicable requirements and/or principles set out in:

- IFPMA Code of Practice
- EFPIA Code of Practice
- the World Health Organization's Ethical Criteria for Medicinal Drug Promotion
- Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC
- the Human Medicines (Amendment) (No2) Regulations 2014 No.1878



2. Principles and agreements

Principles for working together

The ABPI/National Voices guide, “[Working Together, Delivering For Patients](#)” sets out four guiding principles that should underpin all collaborative working between industry and patient organisations:

- ❖ **Clarity of purpose:** each party should be clear about the reason for and the planned outcome of the collaboration – and the ultimate benefit for patients
- ❖ **Integrity:** each party should act, and be seen to act, honestly and with integrity at all times
- ❖ **Independence:** each party should maintain their independence
- ❖ **Transparency:** each party should be open and honest about the purpose of the collaboration and be able to account publicly for the associated activities and any exchanges of funding

When thinking about setting up a new industry-patient partnership, it is helpful to test your thinking against these four interlocking principles. Asking questions like the ones below can assist the development of your plans:

- ❖ Why do we want to work together?
- ❖ How will patients and the health system ultimately benefit?
- ❖ How will we agree the desired outcomes and evaluate them?
- ❖ Why, how and when will we involve patients?
- ❖ How will this project benefit my organisation?
- ❖ How will we retain independence whilst working together and making decisions, e.g. on the scope of work?
- ❖ What money or benefit transfers are involved?
- ❖ What will being transparent involve?

What the ABPI Code says

The 2021 ABPI Code has been set out in an updated format with information applicable to interactions and relationships with patient organisations and individuals representing patient organisations now incorporated in the grey, yellow, pink and teal sections of the Code. The grey section of the code covers ‘Overarching Requirements’. This section provides standards which apply broadly to interactions and relationships with definitions key to understanding the code set out in Clause 1, including for Patient Organisations and Individuals representing patient organisations :-

Clause 1.15 ‘Patient organisation’ means 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.

Clause 1.16 ‘Individuals representing patient organisations’ means a person who is mandated to represent and express the views of a patient organisation.

Clause 27 sets out some requirements which are specific to working with patient organisations. It states that companies must:

- respect the independence of the organisations
- assure the independence of the organisations, in terms of their political judgement, policies and activities
- ensure relationships are based on mutual respect, with the views and decisions of each partner having equal value
- not promote or request the promotion of a particular prescription only medicine
- ensure the objectives and scope are transparent and support provided by companies must always be clearly acknowledged.

Clause 27.2 sets out the requirements for a written agreement to be in place for each donation, grant, or sponsorship setting out exactly what must be included as captured in the table 1 below.

Clause 27.3 states when providing donations, grants or sponsorship (including in relation to events/meetings) to patient organisations, companies must ensure:

- they comply with the prohibition on advertising prescription only medicines to the public
- that the involvement of the company is made clear and that all of the arrangements comply with the Code. This includes the need to declare the provision, and the wording of the declaration must accurately reflect the nature of the company’s involvement.

27.4 states that a company must not seek to influence the text of patient organisation material in a manner favourable to its own commercial interests. This does not preclude a company from correcting factual inaccuracies.

Table 1:

Clause 27.2 Requirements for the written agreement for each donation, grant or sponsorship must include:	
A description of the donation, grant or sponsorship	<input type="checkbox"/>
The objective including how it will support healthcare, scientific research or education	<input type="checkbox"/>
The names of the organisations/parties involved and their respective roles	<input type="checkbox"/>
Type of activity and the nature of the company's contribution (e.g. donation, grant, sponsorship of a specific meeting or publication etc)	<input type="checkbox"/>
Time Frame	<input type="checkbox"/>
Amount of funding and/or a description of indirect/non-financial, in-kind donation and the nature of that donation (e.g donation of agency time or free training courses). Where possible full breakdown of costs	<input type="checkbox"/>
Statement that all parties are fully aware that the donation, grant or sponsorship must be clearly acknowledged and apparent from the start	<input type="checkbox"/>
Signatories to the agreement	<input type="checkbox"/>
Date of the agreement	<input type="checkbox"/>

In addition to Clause 27 requirements, the written agreement must be certified as set out in Clause 8.3. A company must ensure that any materials, activities etc resulting from working with patient organisations are also certified where these are covered in Clause 8.3.

Working together with one or more companies

Pharma companies can work with patient organisations in other areas beyond grants, donations and sponsorship e.g., fee for service, contracted activities and ‘collaborative working’

The ABPI Code states ‘Collaborative working’ refers to pharmaceutical companies working with other organisations to deliver initiatives which either enhance patient care or are for the benefit of patients or alternatively benefit the National Health Service (NHS) and, as a minimum, maintain patient care.

The ABPI Code sets out that Collaborative working between the pharmaceutical industry and healthcare organisations with the goal of enhancing patient care, benefiting patients and/or benefiting the NHS is acceptable, providing it is carried out in a manner compatible with the Code.

Collaborative working projects may involve working with a patient organisation and in such circumstances, the arrangements for the patient organisation involvement must comply with Clause 27 and is likely to be a contracted service (Clause 24), as set out in Clause 27.5. Therefore, a patient organisation must not be a party of the collaborative working agreement. This is to ensure patient organisation involvement is separate and the transfer of value is disclosed as a clear and separate interaction. Further, as a collaborative working project may explicitly reference and/or use a company’s medicinal product it would not be appropriate for a patient organisation to be involved as part of the overall project, including the contract.

When working with a patient organisation a company cannot insist that it is the sole funder or sponsor of a patient organisation, nor make its support conditional on it being the sole funder. However, it may find itself the only company wishing to support a particular patient organisation or its activities.

Many patient organisations are supported by a number of pharmaceutical companies. However, a patient organisation may choose to work with just one commercial organisation, for example in a project focused on a rare disease. The [IFPMA Code of Practice](#) covers this issue in its Q&A section (page 55).

Where companies contract with individuals representing patient organisations to provide services, such contracts should be made with the patient organisation, and payment should be disclosed as a payment to the patient organisation.



Clarity in written agreements

Whilst large patient organisations may be familiar with agreements and have the resources to draft and review them, individuals or small organisations may not. Use plain English and take care not to exclude people or groups inadvertently by developing an over-complex document. The [Plain English Campaign](#) is a good source of writing guides, including one on medical information.

Patient Focused Medicines Development, the Workgroup of European Patient Advocacy Networks (WECAN) and Myeloma Patients Europe have developed a guide: [Reasonable Agreements between Patient Advocates and Pharmaceutical Companies](#). Their work addresses the concern that agreements are often too long or complex and can put patient organisations or advocates in a vulnerable position. Note: This guide has not been assessed in relation to the 2021 ABPI Code of Practice.

Single point of contact

It is very helpful if a company can provide a consistent and single point of contact for the patient organisations it plans to work with, and takes time to support them through the process: commercial structures can be complicated for others to navigate, and representatives of patient organisations often have very limited time or resources to devote to administration.

The Association of Medical Research Charities (AMRC) recommends that “charities should aim to have an established point of contact in their partner company and a specific member of staff who leads on managing the relationship.”([AMRC \(2014\) An Essential Partnership: A guide for charities working with industry](#). London: AMRC.)

3. Definitions of participants



In projects where pharmaceutical companies and patient organisations work together, roles need to be defined precisely as this will have an impact on what information you can share with whom and how you can work with them. A person or group may be defined in more than one way depending on the role and responsibilities they have in a particular activity.

What the ABPI Code says

The ABPI Code states that “prescription-only medicines must not be advertised to the public” (Clause 26.1), reflecting UK regulations relating to advertising.

The “public” includes individual patients. Sometimes the term “patient” is replaced by “people affected by” or “consumer”.

The ABPI Code defines ‘Patient Organisations’ in Clause 1.15:

“ 1.15 ‘Patient organisation’ means 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.”

Additional sources of guidance

EFPIA gives the following definition of **patient organisations** in its Code of Practice on relationships between pharma and patient organisations:

“ Patient Organisation (PO): non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe.

Patient Organisation Representative: is a person who is mandated to represent and express the collective views of a PO on a specific issue or disease area.”

The European Patients' Academy on Therapeutic Innovation (EUPATI) uses the term “**patients**” to cover all the following definitions:

◆ “**Individual patients**” are persons with personal experience of living with a disease. They may or may not have technical knowledge in R&D or regulatory processes, but their main role is

to contribute with their subjective disease and treatment experience.

◆ “**Carers**” are persons supporting individual patients such as family members as well as paid or volunteer helpers.

◆ “**Patient advocates**” are persons who have the insight and experience in supporting a larger population of patients living with a specific disease. They may or may not be affiliated with an organisation.

◆ “**Patient organisation representatives**” are persons who are mandated to represent and express the collective views of a patient organisation on a specific issue or disease area.

◆ “**Patient experts**”, in addition to disease-specific expertise, have the technical knowledge in R&D and/or regulatory affairs through training or experience, for example EUPATI Fellows who have been trained by EUPATI on the full spectrum of medicines R&D.

The term “**expert patients**” or “**patient experts**” has no legal standing, and can refer to different aspects of expertise. There are many different definitions of an expert patient, including the technically trained patient in the EUPATI definition above; or someone who

has taken part in a course on self-management for people with a long-term condition. Some definitions focus on the skills and experience of the patient in terms of their ability to communicate confidently and effectively, perhaps taking a broader view based on more than just their own experience. It could be a combination of experience of an illness, plus the wider knowledge of current thinking about a disease, and the ability to communicate meaningfully in a way that helps educate pharmaceutical companies and health professionals. For example, a patient who has participated in many events may have expertise in

best practice for patient involvement, in what makes for a good conference experience for patients and what matters most for patients with their health condition.

The table below (from [The Expert Patient: towards a novel definition – Jean Francois Cordier, The European Respiratory Journal](#)) gives some useful examples of the different skills that could define expert patients; they might have different combinations of academic as well as experiential skills and may help to determine the skills required when seeking an expert patient or patient expert:

Experiential and academic skills that define expert patients

Table 2:

Experiential	Academic
Personal knowledge of illness and treatment	Knowledge of the disease and treatment
Education as a patient, including self-management	Academic education as an educator/teacher
	Participation as an educator/teacher with health professionals in patient education, including self-management, and taking into account patient values and priorities for clinical decision-making
Collaborative relationship with the general practitioner and proximity specialist	Collaborative relationship with academic specialists
Membership of patient associations	Responsibilities in patient associations (e.g. as a board member)
Attendance at local patient meetings	Attendance and active participation in regional/national/international patient meetings
Participation (as a patient) in clinical studies/therapeutic trials	Participation as a partner in the design of clinical studies/therapeutic trials
Dispute resolution procedure	Executive sponsor oversight from each party

This list is not exhaustive (e.g. expert patient participation in physician education should be considered).

In its publication [Working Together: An Essential Guide](#), the Patients' Association recommends asking what is appropriate for a specific situation when agreeing definitions:

“ Whilst it is important to be aware of semantics, it is perhaps of greater importance to be aware of the context in which you are working. Individuals should be asked at the beginning of any project how they would like to be identified. This will help to ensure people involved have a form of self-identity they feel comfortable with, and empowered by.”

When developing definitions, asking questions like the ones below can help to clarify roles:

- ◆ What is the purpose of communicating with an individual or group?
- ◆ Will I be giving or receiving information?
- ◆ What information will I be passing on?
- ◆ Could this be viewed as promotional material?
- ◆ What skills, experience or other qualifications am I looking for?
- ◆ How will I consider and use the information and feedback I receive?



4. Events and meetings

Patients and individuals representing patient organisations can add personal experience and a welcome perspective to meetings and events including conferences, congresses and clinical trial days.

What the ABPI Code says

Clause 10.3 of the ABPI Code states that there must be a written agreement in place for sponsorship of patient organisations (including individuals representing patient organisations to attend events/ meetings) including, where possible, a breakdown of agreed costs

Note: Clause 27.2 of the Code outlines requirements for the written agreement.

When considering an event/meeting check your plans against Clause 10.1 to ensure it fulfils the Code's following requirements:

Table 3:

Event/Meeting requirement checklist:	
The meeting must have a clear educational content, it should be the programme that attracts delegates to attend and not the associated hospitality or venue	<input type="checkbox"/>
The content must be appropriate and relevant to attendees	<input type="checkbox"/>
The venue must be appropriate and conducive to the main purpose of the meeting; lavish, extravagant or deluxe venues must not be used.	<input type="checkbox"/>
Any associated subsistence (food and drink), accommodation and travel costs must be strictly limited to the main purpose of the event/meeting, must be of secondary consideration and must be appropriate and not out of proportion to the occasion	<input type="checkbox"/>
Companies must not sponsor or organise entertainment for the meeting (such as sporting or leisure events) and companies should avoid using venues that are renowned for their entertainment facilities.	<input type="checkbox"/>
Any hospitality provided must not extend to an accompanying person unless that person qualifies as a proper delegate or participant at the meeting in their own right, or is a carer. In exceptional cases of established clear health needs of the delegate (eg disability or injury), similar hospitality may be provided for an accompanying person.	<input type="checkbox"/>

Requirements for disclosure of payments

The ABPI Code also sets out key considerations regarding the requirements for the disclosure of payments or sponsorships of patient organisations; or individuals representing patient organisations to attend meetings and events, as follows:

Table 4:

Clause 10.2 - No payment may be offered or paid to individuals merely for their time spent in attending events/ meetings	<input type="checkbox"/>
Clause 29.1 - 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. Each reporting period shall cover a full calendar year. Each company must include a note of methodologies used by it in preparing the disclosures and identifying support and contracted services provided.	<input type="checkbox"/>
Clause 29 of the Code sets out all details regarding disclosure requirements, and this should be referenced and followed.	<input type="checkbox"/>

Clause 29, 30 and 31 of the Code also set out all details regarding disclosure requirements, and these should be considered.

Sharing information when patients are present

At some events there may be a mixed audience consisting of both health professionals and lay people. Many pharmaceutical companies and patient organisations worry about what can be shared when patients are in the room.

The ABPI Code's principle on sharing information with the general public still stands: promotion of prescription-only medicines is not permitted.

That means that promotional presentations suitable for health professionals are not appropriate for patients. Clause 26 of the ABPI Code and its associated supplementary information provides detailed information about what can be shared with the public.



Planning events involving patients

The purpose of patient or patient organisation involvement at an event should be articulated well in advance, and agreement sought on the respective roles and responsibilities of companies and patient organisations. Aim for a shared, joint solution that respects the interests of all parties and complies with all Code requirements.

When planning an event involving patients, consider inclusion and access requirements for the venue, including by providing a named person for patients or members of the public to liaise with before and during the event, especially if they have additional needs.

Think carefully about the structure of the agenda, timing of Q&As or closing remarks, and signpost which sessions are suitable for which audiences. Descriptive language, restricted access sessions or online areas and passwords will help to make this distinction between sessions for different audiences. Consider how room layout and access can assist with differentiating sessions. If another organisation is hosting the meeting or event, provide feedback on the format to the organising body, ahead of time.

Take care to explain clearly to a patient participant the reasons why certain sessions are not available for patients to attend. Patients can find it confusing or frustrating to be barred from joining or asked to leave a session; or to encounter posters or other material which are covered up to prevent them viewing promotional material for prescription-only medicines.


Social media

Social media is a growing tool used commonly by organisations to raise awareness of certain information which may include meetings, events and disease awareness information. Consideration should be given to any materials or content that is developed and used on social media by pharmaceutical companies. As above, the principle on sharing information with the general public stands.

Clause 26.2 Supplementary Information – Information to the Public includes a statement in relation to social media:

“ Companies should take particular care if they use social media.

Any information so provided must observe the principles set out in this clause; that is, it should be factual, balanced and must not encourage members of the public to ask their doctors or other prescribers to prescribe a specific prescription only medicine. It must not constitute the advertising of prescription only medicines to the public prohibited under Clause 26.1..”





Overseas events

The ABPI Code sets out reasons why a venue outside the UK could be appropriate for a meeting or event involving patients or patient organisations. The supplementary information to Clause 10.1 Events/Meetings held Outside the UK gives context:

The supplementary information to Clause 10.1 Events/Meetings held Outside the UK states: ‘Events/ meetings organised by pharmaceutical companies which involve UK health professionals at venues outside the UK are not necessarily unacceptable. There needs to be valid and cogent reasons for holding the event/meeting at such venues. These are that most of the invitees are from outside the UK and, given their countries of origin, it makes greater logistical sense to hold the event/meeting outside the UK or, given the location of the relevant resource or expertise that is the object or subject matter of the event/ meeting, it makes greater logistical sense to hold the event/ meeting outside the UK. Consideration should be given to the use of technology to avoid travel outside the UK, e.g. webinars, virtual meetings.’

The same requirements relating to appropriateness of event, arrangements for payments and their disclosure, and sharing information apply for overseas events as they do for UK events.

Advisory boards

Companies can arrange advisory board meetings and pay health professionals and others – for example patients or individuals representing patient organisations - for advice on subjects relevant to their products. They should be held to enable companies to answer legitimate business questions to which they do not already know the answer, and where the invited attendees may be able to help with such questions.

Advisory boards cannot be used to promote a company’s medicines and must not be an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

If you plan to invite patients or patient organisations to an advisory board, check that the answer to all the following questions is “yes”. If the answer to any of the questions is “no”, there may be a compliance issue to consider before proceeding.

Does the company have a legitimate unanswered business question?	<input type="checkbox"/>
Is an advisory board the most appropriate way of obtaining the information?	<input type="checkbox"/>
Does every participant have the relevant expertise to contribute meaningfully to the purpose and expected output of the meeting?	<input type="checkbox"/>
Is the number of participants sufficiently small to allow active participation by all?	<input type="checkbox"/>
Does the agenda allow adequate time for discussion? Is a significant majority of the time spent on feedback from the participants?	<input type="checkbox"/>
Has the company wholly and solely determined its need for the advisory board, with no input from expected attendees?	<input type="checkbox"/>
Is the number of delegates/meetings strictly limited to that required to answer the question?	<input type="checkbox"/>
Does the invitation to participate clearly state the purpose of the meeting, the expected advisory role and the amount of work to be undertaken?	<input type="checkbox"/>
Are patient invitees to be paid; if so is the payment at a “fair market value” and is the invitation clear about payment?	<input type="checkbox"/>
Are intended presentations to participants relevant to their role in answering the business question?	<input type="checkbox"/>
Is this the only advisory board to address the specific business question?	<input type="checkbox"/>
Are the participants expected to do any preparatory work?	<input type="checkbox"/>
Are all those involved with the meeting (staff, third parties, participants) clear on the need for, and expected output from, the meeting?	<input type="checkbox"/>

Once you are satisfied that an advisory board meeting involving patients or patient organisations is appropriate and compliant with the ABPI Code, use the checklist below in your planning:

Are the arrangements (e.g. venue, subsistence, travel, contract) appropriate?	<input type="checkbox"/>
How were the participants selected?	<input type="checkbox"/>
Who from, or on behalf of, the company is attending? Do they have a defined role and is the ratio of company employees/others to participants reasonable?	<input type="checkbox"/>
Will there be a conclusions/recommendations report? What use will be made of it?	<input type="checkbox"/>
Have any advisory boards for the same medicine/therapy area already taken place/been planned within, for example, a 12-month period? If so, what is the justification for another one?	<input type="checkbox"/>
What follow-up, if any, is to be undertaken with participants, and is this appropriate for the specific advisory board?	<input type="checkbox"/>
Is this advisory board held in conjunction with any other meeting such as a learned society congress?	<input type="checkbox"/>

5. Research and development

What the ABPI Code says

Written agreements must be in place and companies must disclose details of the patient organisations to which they provide financial or significant non-financial support, under Clause 27.2 of the ABPI Code.

As with any activity, transparency is vital in building and supporting trust. Clause 4.6 and 4.7 of the ABPI Code covers responsibilities in relation to disclosure of clinical trials and non-interventional studies of marketed medicines.

Additional sources of guidance

The Association of Medical Research Charities (AMRC) states in its publication [An Essential Partnership: A guide for charities working with industry](#):

“... charities can play a key role in representing the patient voice because they are in the unique position of having direct contact with patients while at the same time funding medical research.”

The [National Institute for Health and Care Research \(NIHR\) website](#) provides information about public involvement in research and features some practical tools and resources for researchers and others. In April 2020, the NIHR also launched a [Centre of Engagement and Dissemination](#) to bring together its activities in patient and public involvement, engagement and participation with its strengths in research dissemination.

The ABPI is a member of an EU Commission project called [PARADIGM](#) which is identifying the tools needed by both industry and patient and medical research charities to improve public and patient involvement in research and development. PARADIGM is also working to develop metrics to evidence why public and patient involvement in research and development is beneficial.

EFPIA's guide on [Working Together with Patient Groups](#) sets out how patient engagement across the life cycle of a medicine, including at the R&D stage, can provide critical insights, for example in contributing to study design, informed consent forms and layperson summaries. It was developed by the EFPIA Patient Think-Tank (PTT) in collaboration with EFPIA's Ethics and Compliance Committee and provides helpful suggestions and solutions for some of the challenges.

6. Product launches



Many companies consider working with patients on shaping input to new product launches. Sharing patient stories internally can be really useful and help employees to develop a detailed understanding of the experience of life with a particular condition.

What the ABPI Code says

In terms of compliance, a new product launch is no different to any other activity, and the ABPI Code applies in exactly the same way, with the same requirements, for example around promotion, information, agreements and events.

Patient organisations are naturally keen to learn about new developments in their areas, but again, care has to be taken with ensuring that any information which is shared is not promotional, or for a promotional purpose. (See Clause 26.2 of the ABPI Code for more detail.)

7. Payment

Patient organisations, individuals representing patient organisations, patients, carers etc often devote their time to support and participate in activities with industry.

When this occurs the service, they provide is acceptable providing they are provided for the purpose of supporting healthcare, research, or education; and do not constitute an inducement to recommend, and/or, prescribe, supply, sell or administer a specific medicine. Such services can be remunerated either to the individual or a payment can be made directly to a patient organisation. It is important a written agreement is put in place for such services whether they are to be remunerated or not. Such agreements should be with, and signed by, the individual or organisation the payment is to be made to. This and additional requirements are set out in Clause 24, Contracted Services and should be followed.

Remuneration should be reasonable and not exceed the 'fair market value' of the services provided. "Fair

market value" is not itself defined in the ABPI Code, as the ABPI cannot recommend rates due to competition law.

A fair market value will depend on a number of elements, including the kind of activity being undertaken, the amount of time invested, and the experience and skills of the people involved. Whilst high-level principles can shape thinking, all payment decisions including when to pay and how much are the responsibility of individual companies.

Whilst there is a strong public health and patient benefit rationale for engagement between pharmaceutical companies and patient organisations, any relationship between patient organisations and the pharmaceutical industry can also be perceived as commercially motivated, as the EFPIA guide [Working Together with Patient Groups](#) notes. So the principles of clarity, integrity, independence and transparency are critical in respect of payments, along with adherence to Code requirements.

What the ABPI Code says about Disclosure

The ABPI Code includes the importance of transparency with regard to transfers of value including payments, and on having written agreements in place irrespective of whether a payment is to be made.

Clause 29.1 states that companies must make publicly available annually, a list of the 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 at a national or European level. Each reporting period shall cover a full calendar year. Further each company must include a note of methodologies used by it in preparing the disclosures and identifying support and contracted services provided.

The relevant requirements for disclosure of donations, grants and sponsorship (including in relation to events/meetings) provided to Patient Organisations,

and payments for contracted service by patient organisations, the public, patients and the media are covered in ABPI Code Clauses 29, 30 and 31.

A template to disclose the information required in relation to patient organisations is available from the PMCPA website www.pmcpa.org.uk. The use of this template is optional.

Disclosure UK. Companies may additionally choose to submit their patient organisation disclosure web page link to the ABPI's existing transparency database, [Disclosure UK](#). A list of links to patient organisation disclosures on individual company websites is published annually via Disclosure UK. Providing this link is not mandatory for pharmaceutical companies covered by the ABPI Code, although it is supported by the [2021 ABPI Principle on Transparency](#) and backed by the ABPI Board. For more information about the patient organisation 'gateway', visit the [Disclosure UK resources](#).

The Public, Including Patient 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.

A template to disclose the information required in relation to patient organisations is available from the PMCPA website www.pmcpa.org.uk. The use of this template is optional.

Clause 31 sets out the Timings, Duration and Retention of Disclosure Information

- 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.

Additional sources of guidance

The EFPIA Patient Think Tank (PTT) is developing further guidance (non-legally binding and complementary to the EFPIA Code) on the remuneration of patients, patient organisation representatives and carers for work undertaken with pharmaceutical companies and associations.

A set of principles and criteria for establishing levels of remuneration is being developed, co-created by representatives of patient organisations and the research-based pharmaceutical industry through the PTT in collaboration with the EFPIA Ethics and Compliance Committee, WECAN and Patient Focused Medicines Development (PFMD).

The [NIHR website](#) provides practical advice on paying and recognising the contributions of members of the public and offers a range of guides, calculators and other information. While the resources are designed to support involvement in research, the general principles have wider application.

Companies should be mindful that patients value consistency, transparency and a rationale for payments they receive as compensation (reimbursement of expenses is additional, and not the same as compensation). They may need to declare payments for tax, and payments may also impact on any state benefits received.

8. Conclusion

We hope this sourcebook gives you some practical guidance on core principles and some key areas of compliance; and where to go for more advice when working together with patients and patient organisations.

Whilst this sourcebook provides informal guidance, it remains the responsibility of companies to ensure that they comply with the most up-to-date version of the ABPI Code. Ways of working together between pharmaceutical companies and patient organisations continue to develop.

We aim to update the sourcebook on a regular basis with information and pointers to guidance, as well as any changes to the ABPI Code.

We would appreciate any comments and feedback on this sourcebook to feed into future editions.

Appendix: Further information and sources

ABPI: [Code of Practice](#)

ABPI/National Voices: [Working Together, Delivering For Patients](#)

AMRC: [An Essential Partnership: A guide for charities working with industry](#)

Change Foundation: [Should Money Come Into It?](#)

[Disclosure UK](#)

EFPIA: [Health Collaboration Guide 2017](#)

EFPIA: [Working Together with Patient Groups](#)

[European Patients' Academy on Therapeutic Innovation](#)

European Respiratory Journal: [The Expert Patient: towards a novel definition](#)

IFPMA: [Code of Practice 2019](#)

Innovative Medicines Initiative: [PARADIGM](#)

[National Institute for Health and Care Research](#)

[Patients' Association](#)

Patient Focused Medicines Development, Workgroup of European Patient Advocacy Networks, Myeloma Patients Europe: [Reasonable Agreements between Patient Advocates and Pharmaceutical Companies](#)

[Plain English Campaign](#)

[PMCPA – Prescription Medicine Code of Practice Authority](#)

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- Pfizer
- Takeda
- TEVA
- UCB
- Action Kidney Cancer
- AMRC
- Asthma + Lung UK
- Cancer 52
- Cystic Fibrosis Trust
- Diabetes UK
- UK Gout Society
- The Haemophilia Society
- Kidney Research UK
- MPS Society
- National Voices
- NCRI
- NIHR
- Pain UK
- Parkinsons UK
- Primary Care Rheumatology and Musculoskeletal Medicines Society
- Versus Arthritis

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