

# Working together:

a handbook for industry  
and patient organisation  
partnerships

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# About us

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## The Association of the British Pharmaceutical Industry (ABPI)

The ABPI exists to make the UK the best place in the world to research, develop and access medicines and vaccines to improve patient care. We represent companies of all sizes that invest in making and discovering medicines and vaccines to enhance and save the lives of millions of people around the world. In England, Scotland, Wales and Northern Ireland, we work in partnership with governments and the NHS so that patients can get new treatments faster and the NHS can plan how much it spends on medicines. Every day, our members partner with healthcare professionals, academics and patient organisations to find new solutions to unmet health needs.

**[www.abpi.org.uk](http://www.abpi.org.uk)**



**Patient  
Information  
Forum**

## The Patient Information Forum (PIF)

The PIF is the independent membership body for people working in health information and support in all sectors. It is the independent voice of UK health information. PIF sets standards for health information and operates the PIF TICK – the independent quality mark for health information. Our vision is that everyone has access to personalised health information and support to enable them to make informed decisions about their health, wellbeing and care.

**[www.pifonline.org.uk](http://www.pifonline.org.uk)**

# Foreword

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Patient organisations represent the best interests of people with lived experience. They have taken years to build their patient and clinical communities, developing expertise in supporting patient and public involvement.

Partnerships between health charities and pharmaceutical companies can bring huge value in helping support patient communities.

The ABPI Code of Practice sets out the core principles pharmaceutical companies must follow in the UK, including when working and communicating with patients and patient organisations, and the aspiration that everything they do will ultimately benefit patients. This aspiration touches every aspect of discovering, developing and bringing new medicines and vaccines to patients.

For companies, working in partnership with patients and patient organisations can bring a better understanding of patients' experiences and unmet needs, improve knowledge of healthcare delivery, develop relevant outcome measures and inform strategic aims and direction.

The value of partnership and patient and public involvement is now routinely recognised and undertaken across the life cycle of medicines, from research to delivery of new and established treatments. This aligns with the quality criteria and approach of the PIF TICK for health information. Health information should be evidence-based, user friendly, comply with regulatory requirements and be developed with users. Both patient organisations and pharmaceutical companies can be certified by PIF TICK.

It is vital that partnerships are compliant with regulation. The four key principles of the ABPI Code of Practice underpin any engagement. Partnerships should have **patient benefit** and they should be conducted with **integrity, transparency** and **treat all stakeholders with respect**.

Compliance issues can be challenging and can be perceived to be a barrier to partnership work. This handbook is designed to help you overcome that challenge and create fair and compliant partnerships that bring benefits for all parties.

This is a crucial time for trusted health organisations to work together. Misinformation and disinformation on health, medicines and vaccines is a threat to health. We should work collaboratively as trusted partners to overcome this. We hope that this resource is a valuable tool for patient organisations and companies to enable successful partnerships that deliver better experiences and outcomes for patients.



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# Introduction

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The ABPI supports and encourages industry and patient organisations working together. The introduction to the ABPI Code of Practice states:

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

Patient organisations are also supportive of partnership:

**“There is a growing desire from commercial and public sector organisations to actively involve people with lived experience in the development of their activities. It is encouraged and very much supported by charities.” Fair market value for charities in partnership work.**

This handbook is designed to support pharmaceutical companies and patient organisations to work together in the interests of patients and within the standards set in the 2024 ABPI Code of Practice.

The aim of this handbook is to bring together practical tools, tips and further sources of information to support good practice. It will 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 handbook to help you work together.

## How this handbook was developed

The handbook was first published in 2018 to sit alongside the ABPI Code of Practice to support successful engagement between industry and patient organisations. Since then, there has been a growing emphasis on patient and public involvement in the medicines lifecycle and partnership work has expanded.

In 2024, the ABPI Code was updated. The ABPI and the Patient Information Forum have worked together to review the handbook. We consulted people working in the pharmaceutical industry and patient organisations to ensure the update meets the requirements of the new ABPI Code and supports partnership working.

**Note:** If you are interested in understanding how partnerships between industry and NHS organisations are established and managed, please refer to the following guidance, co-produced by the ABPI and NHS Confederation: [Accelerating transformation: How to develop effective NHS-industry partnerships | NHS Confederation.](#)

# Understanding the regulatory framework

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The regulatory framework for medicines is complex and not all patient organisations will be familiar with all the requirements. The Medicines and Healthcare products Regulatory Agency (MHRA) sets the regulatory framework for medicines in the UK. The promotion of prescription medicines to the public is prohibited. The definition of promotion is much wider than advertising alone. The ABPI Code of Practice is a self-regulatory code that regulates the promotion of medicines in line with MHRA rules. The ABPI Code reflects UK law and in some areas is stricter than the law.

## What is the Medicines and Healthcare products Regulatory Agency?

The MHRA is a government agency. It regulates medicines, including vaccines, supplied in the UK. It regulates the whole of a medicine's lifecycle. It decides whether medicines should be granted licences based on safety, quality and effectiveness data. It is responsible for enforcing the advertising regulations for medicines in the UK, and like most countries, prohibits the promotion of prescription medicines to the public.

## What is the Association of the British Pharmaceutical Industry?

The ABPI represents pharmaceutical companies of all sizes that invest in making and discovering medicines and vaccines. The more than 60 ABPI member companies agree to comply with the ABPI Code as a condition of membership. In addition, around 100 other pharmaceutical companies have signed up to abide by the ABPI Code.

## What is the ABPI Code?

The ABPI Code of Practice (referred to throughout as the ABPI Code or the Code) was first published in 1958. It exists to regulate the promotion of prescription medicines to UK health professionals, industry interactions with health professionals, and the provision of information about prescription-only medicines to the public.

It is updated regularly in consultation with the MHRA, the British Medical Association, the Royal Pharmaceutical Society, the Royal College of Nursing, the Competition and Markets Authority and the Serious Fraud Office. A public consultation on any changes proposed is also conducted. The ABPI Code was last updated in 2024.

Four core principles underpin the ABPI Code:

- Industry must work for **patient benefit**
- with **integrity**
- and **transparency**
- and **treat all stakeholders with respect**

## **What is the Prescription Medicines Code of Practice Authority (PMCPA)?**

The ABPI Code is administered by the PMCPA. It was established to operate independently of the ABPI. It is the cornerstone of the UK system of industry self-regulation. The PMCPA is responsible for the provision of advice, guidance and training on the ABPI Code as well as handling and adjudicating for the complaints procedure. Its case reports provide further guidance and interpretation of the ABPI Code.

Relationships between industry and patient organisations are bound by the ABPI Code and underpinned by UK law.

“The Code serves as a guardrail by which industry is regulated to ensure that throughout all partnership working, patient safety is maintained in a professional, ethical and transparent manner to ensure the appropriate provision of high-quality care. The ABPI works closely with ABPI members and patient charities to foster partnership working in line with the Code.”

**Dr Amit Aggarwal**, Executive Director,  
Medical Affairs and Strategic Partnerships,  
ABPI

# The ABPI Code of Practice – relationships between patient organisations and industry

The ABPI Code applies to most UK pharmaceutical companies. It is valuable for patient organisations to be aware of the Code because it sets the parameters for what pharmaceutical companies can and cannot do and the standards they must meet.

When pharmaceutical companies and patient organisations work or interact together, the scope of the work and interaction, as well as individual roles, need to be precisely defined. To aid this, the ABPI Code sets standards for the following:

- 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 key clauses relating to industry and patient organisation partnership are listed below.

**Tip:** Clauses 1 and 27 are a good place to start to understand the Code as they provide an overview of the key requirements governing relationships between pharmaceutical companies and patient organisations

## 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 medicines advertising regulations](#). The ‘public’ includes individual patients. In some materials and guides the term ‘patient’ is replaced by ‘people affected by’ or ‘consumer’. There is a complete prohibition on inducements and inappropriate payments under the ABPI Code.

**Clause 1 defines certain terms – those most relevant to patient organisations are:**

**Clause 1.17 defines ‘promotion’** as any activity undertaken by a pharmaceutical company or with its authority that promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

It includes:

- the provision of hospitality for promotional purposes
- the sponsorship of promotional events/ meetings
- the sponsorship of scientific events/ meetings, including payment of travelling and accommodation expenses in connection therewith
- all other promotion (see section 3 of this handbook ‘Common partnership activities’)

Pharmaceutical 'promotion' as defined above in Clause 1.17 is very broad and includes scenarios that may fall outside of what is typically thought of as 'advertising'.

**Clause 1.15 'patient organisation'** means an organisation mainly comprising 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 'individual 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 for pharmaceutical companies working with patient organisations

**Clause 27.1** sets out some requirements for working with patient organisations or any user organisations such as disability organisations, carer or relative organisations and consumer organisations. 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 is clearly acknowledged on materials and outputs

**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 table 1 on page 15.

**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 of funding. The wording of the declaration must accurately reflect the nature of the company's involvement.

**Clause 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.

## The status of patient organisations

The terms used to describe people with lived experience and those used to describe not-for-profit organisations are context-dependent and complex. The guidance, [Fair Market Value for Charities in Partnership Work](#), published by a coalition of charities, acknowledged that different groups prefer different terminology but set this broad definition:

**Health charity:** an organisation whose primary objectives are philanthropy and social well-being. Other terms that may be used include 'not-for-profit organisation', 'third-sector organisation' and 'patient organisation'.

In the UK, patient organisations have different legal statuses and regulatory bodies. Most will be registered charities and regulated by the relevant national charity regulator in the four nations. They will have defined charitable objects and beneficiaries. They must demonstrate sound financial management and public benefit from their activities.

National charity regulators recognise effective charities incur operational costs and encourage a pragmatic approach to managing these. For example, the Charity Commission for England and Wales states, "charities' costs must be 'justifiable and in the best interests of the charity'".

There is a responsibility for charities to ensure all funds they raise are spent appropriately and deliver tangible benefit for their beneficiaries. Charities are keen to ensure that relationships with industry are fair and underpinned by transparency and integrity.

Other patient organisations may be set up as not-for-profit companies and be regulated by Companies House. Smaller organisations may have more informal structures, however, pharmaceutical companies may be unable to support patient organisations who do not hold charitable or not-for-profit status.

It is important to remember that patient organisations must meet their own regulatory requirements for operations and reporting, which are entirely separate to requirements for pharmaceutical companies laid out in the ABPI Code.

## Working with patient organisations as partners

Charities have huge value as partners. A project led by Versus Arthritis and seven other patient organisations in 2023, [From Transactional to Truly Collaborative](#), reported that pharmaceutical companies found working with patients and patient organisations beneficial.

Benefits included:

- gaining a better understanding of patients' experiences and unmet needs
- raising awareness and motivating staff
- improving knowledge of healthcare delivery
- developing more relevant outcome measures
- informing strategic aims and direction

In the health sector, patient organisations are trusted parties, representing the best interests of people with lived experience. The relationships charities build with their patient and clinical communities take many years. Charities have developed expertise in supporting patient and public involvement and in ensuring people with lived experience are effectively informed, supported and have access to a holistic set of services.

The guidance, [Fair Market Value for Charities in Partnership Work](#), provides these definitions for involvement and people with lived experiences:

**Involvement:** any initiative where a person with lived experience influences decision making or the design or delivery of an intervention by a charity or other type of organisation. In some settings this is referred to as patient and public involvement, or PPI.

**People with lived experience:** a person who has first-hand experience of the problem a charity or its partner is seeking to address through its work. This term includes service users, patients, carers and family members.

There is a growing desire from commercial and public sector organisations to actively involve people with lived experience from diverse backgrounds in the development of their activities. This includes all aspects of medicines development, research, service development, health information development and related projects. The PIF provides [guidance on good practice in co-production](#). User involvement is a requirement for companies and patient organisations certified by the [PIF TICK](#) quality mark for health information.

The importance of offering payment to people with lived experience for their involvement is now recognised. There are several sources of guidance about payment to individual PPI contributors. See the appendix for links to this guidance.

**Note:** The ABPI cannot advise on or set payment rates. These must always be a matter for contract negotiation, but this handbook contains a number of resources to assist with determining fair market value. (see appendix)

# A pathway to working together

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## 1. Where can partnerships start?

The ABPI and PMCPA set out four guiding principles that should underpin all working between industry and patient organisations:

**Clarity of purpose:** each party should be clear about the planned outcome 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 must 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 these questions can help develop your plans:

- Why do we want to work together?
- How will patients and the health system ultimately benefit?
- How will each organisation demonstrate public 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 while working together and making decisions, e.g. on the scope of work?

- What money or benefit transfers are involved? Are they fair? How will funding be declared? What will being transparent involve?
- Are there any conflicts of interest?
- How will this partnership be communicated? This includes declaration of funding on any materials, statement of partnership on charity/company website.
- How will we provide feedback to people, patients and the public who might be involved?

The guidance, [Fair Market Value for Charities in Partnership Work](#), recommends patient organisations consider how their strategic aims and values align with the goal of the project or research proposal. It also recommends payments made for partnership work are fair and cover the organisation's operational costs and the value of the charity's involvement.

### Consider a single point of contact

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.

Company processes vary and having a single point of contact to support patient organisations to navigate company processes can help to address this.

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."

## 2. Scoping and agreements

### Different types of partnership funding

There are different ways industry and patient organisations can work together. Some definitions are provided below.

#### Grants

Grants are defined in Clause 1.5 and the requirements are set out in Clause 23.

There are two main types of grants (the provision of funds) provided to organisations, These are educational grants and research grants.

#### Educational grants

An educational grant is funding provided by a pharmaceutical company to support independent educational programmes. Examples of activities for which an educational grant might be given include:

- funding for an organisation to run independent education programmes, seeking to improve practice and outcomes for patients
- funding to produce a leaflet about a disease

#### Research grants

Research grants take the form of funding offered by pharmaceutical companies for the purpose of improving or developing medical or scientific knowledge and understanding. Examples include:

- research into how a medicine works in a small group of patients with a specific type of a disease

- research into how patients are diagnosed and treated for a disease
- research into how patients are affected by a disease

#### Donations

Donations are defined in Clause 1.5 and the requirements are set out in Clause 23.

Donations are generally physical items, services or benefits-in-kind, which may be offered or requested.

Companies provide donations to organisations for improvements or for equipment and products that benefit everyone. These types of benefits or services must be for one of the purposes set out in Clauses 23.1 and 23.2 – to improve the quality and availability of healthcare, educate individuals, support those most at risk of health problems or improve knowledge in science, medicine and health care. Examples of donations are:

- medical equipment or books
- charitable donations to improve waiting areas and/or wards for groups of patients or their families to ensure their treatment experience is as positive as it can be at a difficult time
- free products, where permitted, to support disaster relief

**Note:** grants and donations are given to organisations for the purpose of supporting healthcare, scientific research or education, with no consequent benefit to the recipient organisation to benefit the pharmaceutical company in return.

## Sponsorships

Sponsorships are defined in Clause 1.22 and requirements set out in Clause 25.

Companies specialising in particular therapy areas may provide funds directly to an organisation or through a third-party event organiser to support education for patients, carers, doctors, nurses, pharmacists and other healthcare professionals.

## Contracted services

Contracted services – Clause 24 sets out requirements for contracted services (fees for service).

An organisation may be contracted as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, or participation in advisory board meetings.

## What the ABPI Code says

**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 (see table 1 under the next section, 'Clarity in written agreements'). This must be certified (approved) by the pharmaceutical company.

**Clause 8.3** states what materials must be certified.

## Clarity in written agreements

Large patient organisations may be familiar with agreements and have the resources to review them, but this may be more challenging for medium and small organisations.

The guidance, [Fair Market Value for Charities in Partnership Work](#), recommends:

- contracting arrangements should be transparent and simplified
- budget should be provided for independent legal review of lengthy and complex contracts
- payment terms should be 30 days
- fair market value (FMV) rates should be agreed at the outset of a project or partnership

Use plain language in agreements and take care not to inadvertently exclude people or groups by developing an overly complex document. [The Plain English Campaign](#) is a good source of writing guides, including one on medical information. [The Patient Information Forum](#) also provides guidance on writing in plain language.

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.

**Table 1: What should be included in a written agreement.** ABPI Code Clause 27.2 Requirements for the written agreement for each donation, grant or sponsorship must include:

- description of the donation, grant or sponsorship
- the objective including how it will support healthcare, scientific research or education
- the names of the organisations/parties involved and their respective roles
- type of activity and the nature of the company's contribution (e.g. donation, grant, sponsorship of a specific meeting or publication etc)
- time frame
- 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, a full breakdown of costs
- statement that all parties are fully aware that the donation, grant or sponsorship must be clearly acknowledged and apparent from the start
- signatories to the agreement
- date of the agreement

## Payment, declarations and disclosure

The principles of clarity, integrity, independence and transparency are critical in respect of payments, along with adherence to ABPI Code requirements.

Until recently payments to patient organisations have not been so well defined. A coalition of charities published [research](#) in 2023 and published [recommendations](#) on setting FMV in September 2024. It made five recommendations relating to FMV:

- **Full cost-recovery to support charity sustainability.** Charities need to recover the full cost of their activity including staff costs and central overheads to ensure the sustainability of organisations.
- **Minimum entry point of £100/€120 per hour for the work of charities.** [Patient Focused Medicines Development \(PFMD\)](#) has developed an FMV calculator for people with lived experience.
- **Equity of payment with healthcare professionals where this is higher than the PFMD rate.** The staff of health charities sit alongside healthcare professionals on steering groups and conference platforms. Recognition of this expertise should mean there is equitable payment.
- **Market value add-on costs.** When setting FMV, the intangible 'brand' benefits of partnering with charities should be taken into account.
- **Fair contracting.** FMV rates should be agreed at the outset. Contracts should be transparent and simplified. Payment terms should be 30 days.

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. While high-level principles can shape thinking, all payment decisions including when to pay and how much are the responsibility of individual companies.

### Written agreements

It is important a written agreement covers services whether there is payment or not.

Where there is a payment, agreement should be made with, and signed by, the individual or organisation the payment is to be made to ((see Table 1 on page 15).

### Declarations of involvement

One of the four principles underlying the ABPI Code is **transparency**. This means the pharmaceutical industry must be open about its activities and interactions with all stakeholders and encourage our stakeholders to act with the same openness. In practice, this means company involvement in all materials and activities must be made clear from the outset.

Any activity that has been supported by a pharmaceutical company must be visibly declared. For example, clearly displaying a statement naming the pharmaceutical partners and/or the pharmaceutical company's logo. Real-world examples of declarations can be found on patient education materials such as the [Fight Bladder Cancer policy white paper](#).

**The declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset (this applies to print and digital).**

Before embarking on the activity together, and to avoid disagreements later on, it is advisable to agree at the outset both the wording of the declaration of sponsorship and how prominently it will be cited.

### What the ABPI Code says:

**Clause 27.3** 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 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)**

**Clause 5.6** Declaration of involvement. "The wording of the declaration of involvement must be unambiguous so that readers are immediately able to understand the extent of the company's involvement and influence." This is particularly important when companies are involved in the production of material that is circulated by an otherwise wholly independent party, such as supplements to health professional journals.

**Clause 27.2** “When companies provide donations, grants or sponsorship (including in relation to events/meetings) to patient organisations as set out in Clauses 23.2 and 10, companies must have a written agreement in place for each donation, grant or sponsorship setting out exactly what has been provided.” This includes that written agreements with patient organisations must include... a statement that all parties are fully aware that the donation or grant must be clearly acknowledged and apparent from the start.

## Disclosure of values

Transparency is essential when pharmaceutical companies work with patient organisations. The ABPI Code places disclosure requirements on pharmaceutical companies to publish annually information about financial payments or benefits in kind (also known as ‘transfers of value’) to patient organisations. Currently, there is no similar requirement for those patient organisations in receipt of values from industry to mirror the disclosure on their own websites.

While there is no Charity Commission or legal/regulatory requirement for patient organisations to disclose values received from pharmaceutical companies, patient organisations recognise the importance of transparency, as they would with support from any other grant maker, corporate donor, or sponsor.

Many patient organisations already proactively publish this information as commitment to open and ethical ways of working. They use a range of different approaches to disclose the funding they receive. For example:

- a dedicated disclosure section on their websites
- publishing funding information in annual reports
- including details of any transfers of value within individual project information

The ABPI has put together some best-practice guidance for patient organisations to help them manage or set up their own local disclosure mechanism. The guidance is based on disclosure best practices suggested by patient organisations, which subsequently complement the current mandatory disclosure requirements adhered to by the pharmaceutical industry.

This can be found on the ABPI website: [Best practice guidance: Supporting patient organisations to report industry funding.](#)

## What the ABPI Code says:

### **Clause 29 – Annual disclosure of contracted services, donations, grants and sponsorship (including in relation to events/meetings) provided to patient organisations**

**Clause 29.1** states that companies must make 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 publicly available annually. 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 the methodologies it used to prepare the disclosures and identify support and contracted services provided.

A template to disclose the information required in relation to patient organisations is available from the PMCPA website: [www.pmcpa.org.uk](http://www.pmcpa.org.uk). The use of this template is optional.

### **Clause 30 – Annual disclosure of contracted services provided by the public, including patients and journalists**

**Clause 30.1** states that companies must make details of the fees for certain contracted services paid to members of the UK public, including patients and journalists, publicly available annually. 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 information must be disclosed on the company website. Such disclosures are in aggregate and individuals are not named.

### **Supplementary information (SI) to clauses 29 and 30 regarding the disclosure method**

**SI to clauses 29.1 and 30.1** states that in addition to publishing transfer-of-value information about patient organisations and certain members of the public on companies' own websites, companies must also submit a link via the relevant Disclosure UK 'gateway'. Disclosure UK is the pharmaceutical industry-led transparency database enabling visitors to easily find disclosure information. The gateway link should take visitors from Disclosure UK to the relevant disclosure information published on individual company websites.

**Clause 31** sets out the timings, duration and retention of disclosure information

The declarations must:

- be declared within six months of the end of the calendar year when payments were made
- be publicly available for three years from when they were first disclosed
- be kept for company records for at least five years after the year to which they relate

### Requirements for disclosure of payments to attend meetings and events

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:

**Clause 10.2** – “no payment may be offered or paid to individuals to compensate merely for the time spent in attending events/meetings.”

**Clause 29.1** – “companies must make a list of patient organisations to which it provides donations, grants or sponsorship (including in relation to events/meetings) publicly available annually.”

## 3. Common partnership activities

### 3.1 Disease awareness campaigns

The MHRA recognises the importance of disease awareness campaigns and their ability to provide a valuable source of information to the public on diseases and conditions, aid recognition of symptoms, and highlight appropriate sources of advice.

The MHRA states that the primary purpose of a disease awareness campaign must be to increase awareness of a disease or diseases and to provide health educational information on that disease and its management. It should not promote the use of a particular medicinal product or products.

Disease awareness campaigns should include information that is:

- **accurate** – the information should be carefully checked for accuracy so that the public is not misled
- **up to date** – every effort should be made to ensure that information contained is current; the date of publication should be clear
- **substantiable** – the information should be capable of substantiation by reference to the medical literature or other authoritative sources
- **comprehensive** – balanced and fair; disease awareness campaigns should cover the key characteristics of the disease and ensure that the impact/implications of the disease are realistically conveyed without being alarmist; if appropriate, management options should be presented carefully, in a balanced and fair manner that does not unduly emphasise particular options or the need to seek treatment
- **readable/accessible** – the language used should be designed to convey key messages clearly, supported by appropriate design and formatting
- **source identified** – the source(s) of the campaign should be clearly identified on the publication itself

## What the ABPI Code says

**Clause 26.2** Disease awareness or public health campaigns can be conducted by a company provided that the purpose is to encourage members of the public to seek treatment for their symptoms while in no way promoting the use of a specific medicine. The use of brand or non-proprietary names and/or restricting the range of treatments described in the campaign might be likely to lead to the use of a specific medicine. Particular care must be taken where the company's product, even though not named, is the only medicine relevant to the disease or symptoms in question.

Information on disease awareness campaigns may be proactive, reactive or reference information depending on the circumstances. Attention is drawn to the [Blue Guide Appendix: Disease Awareness Campaign Guidelines](#) produced by the MHRA.

## 3.2 Events and meetings

Medical meetings and events provide an opportunity for people with lived experience to share their experiences of health and healthcare. 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 the companies and patient organisations involved.

The prohibition of the promotion of prescription-only medicines to patients and the public applies equally at congresses.

In practice this might mean restricting access to elements of the meeting to prevent people with lived experience seeing promotional material for prescription only medicines. For example, they may be;

- barred from joining or asked to leave a session
- encounter exhibition booths or other material that are covered up
- excluded from company exhibition areas to prevent them viewing promotional material for prescription-only medicines

This can be frustrating for people with lived experience. Take care to explain clearly to patient participants in advance of an event the reasons why certain sessions are not available for patients and the public to attend.

Aim for a shared, joint solution that respects the interests of all parties and complies with all ABPI Code requirements. Try to ensure people with lived experience benefit as much as possible from taking part in an event within the requirements of the ABPI Code. See the [ABPI's guidance for conferences and events in the UK](#).

### Planning events involving patients

- Think carefully about the structure of the agenda, timing of Q&As or closing remarks, and signpost which sessions are suitable for which audiences.
- Consider how room layout, roped-off areas and access can assist with differentiating sessions, including access to the exhibition area, and where this is placed relative to where patients and members of the public are likely to be.

- Descriptive language, restricted-access sessions or online areas and passwords will help to make this distinction between sessions for different audiences.
- Different coloured lanyards for health professionals and patient organisations delegates can help identify who should be granted access to sessions.
- If another organisation is hosting the meeting or event, provide feedback on the format to the organising body ahead of time.
- When planning an event involving people with lived experience, consider inclusion and access requirements for the venue and online events that help people contribute fully to their best ability, be that providing materials in alternative formats, working with the venue on any audio or visual aids, or translations etc.
- Provide a named person for patients or members of the public to liaise with before and during the event, especially if they have additional needs.

### What the ABPI Code says

**Clause 10.3** 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.

**Clause 27.2** outlines requirements for the written agreement.

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

#### Event/meeting requirement checklist:

- The event/meeting must have a clear educational content; it should be the programme that attracts delegates to attend and not the associated hospitality or venue.
- The content must be appropriate and relevant to attendees.
- The venue must be appropriate and conducive to the main purpose of the event/meeting; lavish, extravagant or deluxe venues must not be used.
- 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 (see Clause 10.8).
- Companies must not sponsor, support or organise entertainment (such as sporting or leisure activities, etc.).
- 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. In exceptional cases of established clear health needs of the delegate (e.g. disability or injury), similar hospitality may be provided for an accompanying person. (See appendix for a pull-out of this checklist)

## Overseas events

For events and meetings where the majority of the delegates are based in the UK the meeting should be hosted in the UK. 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 – see [Clause 10.1 supplementary information](#).

### 3.3 Advisory boards and focus groups

An advisory board or focus group is a group of people invited to a meeting by a company or on behalf of a company to share their advice and insight on a specific topic.

Companies can arrange advisory board meetings 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 a company plans to invite patients or patient organisations to an advisory board, they should 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.

#### Considering whether to invite patients or patient organisations onto an advisory board

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

**Note:** Carers can be engaged to participate in these activities, for example a parent providing the lived experience of their child.

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

#### **Advisory board planning checklist**

- Are the arrangements (e.g. venue, subsistence, travel, contract) appropriate?
- How were the participants selected?
- 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?
- Will there be a summary report? What use will be made of it?
- 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?
- What follow-up is to be undertaken with participants, and is this appropriate for the specific advisory board?
- Is this advisory board held in conjunction with any other meeting, such as a learned society congress?
- Make sure all information provided to participants is in plain language, including invitations, agreements and meeting materials. (See appendix for full checklist)

The same principles will apply to a focus group or round table discussion. All types of group discussion may be on a broader topic or challenge. To ensure correct arrangements are undertaken the checklist is still recommended.

#### **What the ABPI Code says:**

##### **Clause 10 Events/meetings and hospitality**

**Clause 10.1** "Pharmaceutical companies may hold, sponsor or support delegates to attend a wide range of events/meetings, providing such events/meetings meet the requirements of the Code."

**Clause 10.3** "Sponsorship of patient organisations (including individuals representing patient organisations to attend events/meetings) must have a written agreement in place setting out what has been agreed, including, where possible, a breakdown of agreed costs. (The requirements for the written agreement are set out in Clause 27.2.)"

##### **Supplementary information Clause 10.1 events/meetings and hospitality**

"In determining whether any event/meeting is acceptable or not, consideration must also be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, subsistence provided and the like."

### 3.4 Research and development

Involving the public and patients as equal partners in the discovery and development of medicines is vital. The ABPI works with patient organisations and ABPI members to improve how this is done. The ABPI is a proud signatory of a shared commitment to improve public involvement in research, together with other funders, regulators and research organisations who play an important role in UK health and social care research. Together we are committed to:

- listen to and learn from the people and communities we involve, and apply and share that learning
- build and share the evidence of how to involve the public and the impact this has
- support improvements in equality, diversity, and inclusion in public involvement
- promote the UK Standards for Public Involvement

The 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.

The NHS Health Research Authority provides guidance on involvement in research through four core principles. The core principles for meaningful involvement of patients and the public in health and social care research are:

1. Principle 1: involve the right people
2. Principle 2: involve enough people
3. Principle 3: involve those people enough
4. Principle 4: describe how it helps

Research teams that involve patients and the public run better studies because:

- they are more **relevant** to participants
- they are designed in a way that is **acceptable** to participants
- they have participant information that is **understandable** to participants
- they provide a better **experience** of research
- they have better **communication of results** to participants at the end of the study

#### What the ABPI Code says

**Clause 27.2** – "under this clause, 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."

## Additional sources of research insight and guidance

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.

The European Federation of Pharmaceutical Industries and Associations' (EFPIA's) guide 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 in collaboration with EFPIA's Ethics and Compliance Committee and provides helpful suggestions and solutions for some of the challenges.

For further information on inclusivity in research see the appendix.

## 3.5 Product launches

Many companies consider working with patients on shaping input and insight into new product launches.

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 to ensure that any information that is shared is not promotional, or for a promotional purpose.

### What the ABPI Code says

**Clause 26.2** – “information about prescription-only medicines that is made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product.”

“Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription-only medicine.”

### 3.6 Social media

Social media and digital platforms are commonly used by organisations to raise awareness of partnership activities. These 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.

The PMCPA has published [social media guidance](#) that provides more detailed information. The key questions to be explored before undertaking social media activity are covered here.

#### **PMCPA principles for social media activities**

#### **Key questions to consider before carrying out any social media activity:**

- What is the objective of the activity?
- What content will be made available?
  - Is the content related to medicines?
  - Is the content promotional or non-promotional?
  - Does the medicine have a marketing authorisation/is the indication covered by the marketing authorisation?
  - Is the content related to educational information for the public?
  - What information is linked to and therefore forms part of the content?

- Who is the audience (for example, public, health professionals, media, investors) and is the content suitable and appropriately signposted for that audience?
- Are there licence variations between Great Britain (GB) and Northern Ireland (NI)?
- Has access been limited to the appropriate intended audience? Is interaction with the social media activity limited or controlled, and if not how does this affect the risk of the activity?
- Is the audience expected to respond or participate in discussion?
- Is the role of the pharmaceutical company clear?
- How is the content reviewed, approved and maintained?
- What are the arrangements for pharmacovigilance obligations?
- Why could it not be considered as promotion to the public?
- Is it in line with company guidance? Is the company guidance clear and consistent with all applicable codes, laws and regulations? (See appendix for a pull-out of this checklist).

## What the ABPI Code says

### **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...”

## 4. Project delivery and evaluation

Once an activity is delivered it is important to evaluate its effectiveness.

### **Evaluating impact and sharing outcomes**

From the outset of any activity, think how you will measure the benefit and impact of working together. Evaluation of the impact of health information is mandatory for companies and patient organisations certified by PIF TICK. When thinking about impact, look at the aims you set for the activity and how you will measure them. This should include patient and public benefit. Your evaluation should look at the outputs, reach and impact of activities.

There are a range of models that can be used to evaluate activities; these are covered in [PIF's guidance on the evaluation of impact](#).

At the end of the activities, it is good practice to share outputs and evaluation with all parties involved, and where possible to share learnings and case studies.

# Conclusion

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We hope this handbook gives you some practical guidance on core principles for patient organisations and pharmaceutical companies working together, some key areas of compliance and where to go for more advice.

This handbook provides informal guidance, and 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 will continue to develop as patient and public involvement becomes further embedded in the medicines lifecycle.

Patient organisations are invaluable partners in involvement activities at all stages. Fair and transparent practice that contributes to

the sustainability and integrity of the sector is needed to support patient and public involvement; these principles are at the core of the ABPI Code.

We hope this guidance is useful, and look forward to seeing examples of future partnerships that improve the lives of patients. We aim to update the handbook 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 handbook to feed into future editions.



# Appendix and checklists

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## Appendix

### Additional sources of information

#### Considerations for partnership working

ABPI: [Best practice guidance: supporting patient organisations to report industry funding](#)

HRCI / PPI Ignite Network: [Charities & Researchers Partnering Guide](#)

Coalition of Charities (Versus Arthritis and partners) and Pfizer: [From Transactional to Truly Collaborative: Improving Relationships between Industry and Patient](#)

WECAN: [Guiding principles for reasonable agreements between patient advocates and pharmaceutical companies](#)

Association of Medical Research Charities: [An essential partnership: a guide to charities working together with industry](#)

EFPIA: [Working together with Patient Groups \(Sept 2017\)](#) / [Working together with patient organisations \(Sept 2023\)](#)

Charities Research Involvement Group: [Shared Learning Group on Involvement – Encouraging shared learning about service user and carer involvement between voluntary sector organisations working in the UK](#)

#### Digital

PMCPA: [PMCPA Social Media Guidance](#)

#### Fair Market Value

Patient Focused Medicines Development: [Discover tools to support fair remuneration of the patient community for interactions with the pharmaceutical industry](#)

PFMD: [Global Principles for remunerating the patient community for interactions with the pharmaceutical industry](#)

Coalition of Charities (Cancer 52, National Rheumatoid Arthritis Society, Patient Information Forum) Towards Fairer Market Value: [Survey findings](#)

CASS Business School: [Cost recovery, tools for success: doing the right things and doing them right.](#)

#### Research

NIHR: [UK Standards for Public Involvement in Research](#)

EFPIA: [Guide on Working Together with Patient Groups](#). This 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.

EFPIA: [Patient Think-Tank \(PTT\)](#) in collaboration with EFPIA's Ethics and Compliance Committee. Provides helpful suggestions and solutions for some of the challenges.

ABPI: [People-centred research](#). A hub to provide case study examples of work carried out in research to improve inclusivity.



National Voices: [Addressing inequalities in clinical trials](#). A 2024 report exploring the barriers and approaches to addressing inequalities.

IPSOS: [Bridging the ethnicity gap in clinical trial participation: education and tailored communication needs](#). 2024 survey findings and suggestions to tackle inclusivity in research.

NHS England and the Health Research Authority have provided additional guidance:

- NHS England: [Increasing diversity in research participation: A good practice guide for engaging with underrepresented groups](#)
- Health Research Authority: [Increasing the diversity of people taking part in research](#)

## **Conferences and events**

ABPI: [Guidance for conferences and events in the UK: ABPI Code of Practice requirements](#)

## Checklists

### Checklist: Event/meeting requirements

<b>When considering an event/meeting check your plans against Clause 10.1 to ensure it fulfils the ABPI Code's following requirements:</b>	<b>Done?</b>
The event/meeting must have a clear educational content; it should be the programme that attracts delegates to attend and not the associated hospitality or venue.	
The content must be appropriate and relevant to attendees.	
The venue must be appropriate and conducive to the main purpose of the event/meeting; lavish, extravagant or deluxe venues must not be used.	
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 (see Clause 10.8).	
Companies must not sponsor, support or organise entertainment (such as sporting or leisure activities, etc.).	
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. In exceptional cases of established clear health needs of the delegate (e.g. disability or injury), similar hospitality may be provided for an accompanying person.	

## Checklist: Considering whether to invite patients or patient organisations onto an advisory board

If a company plans to invite patients or patient organisations to an advisory board, they should 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.

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

## Checklist: Advisory board planning

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

Advisory board planning	Done?
Are the arrangements (e.g. venue, subsistence, travel, contract) appropriate?	
How were the participants selected?	
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?	
Will there be a conclusions/recommendations report? What use will be made of it?	
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?	
What follow-up is to be undertaken with participants, and is this appropriate for the specific advisory board?	
Is this advisory board held in conjunction with any other meeting, such as a learned society congress?	
Make sure all information provided to participants is in plain language, including invitations, agreements and meeting materials.	

## Checklist: Key questions to consider before carrying out any social media activity

The PMCPA has [published social media guidance](#) that provides more detailed information. The key questions to be explored before undertaking social media activity are covered here.

### PMCPA principles for social media activities

Key questions to consider before carrying out any social media activity:	Done?
What is the objective of the activity?	
What content will be made available?	
◦ Is the content related to medicines?	
◦ Is the content promotional or non-promotional?	
◦ Does the medicine have a marketing authorisation/is the indication covered by the marketing authorisation?	
◦ Is the content related to educational information for the public?	
◦ What information is linked to and therefore forms part of the content?	
Who is the audience (for example, public, health professionals, media, investors) and is the content suitable and appropriately signposted for that audience?	
Are there licence variations between Great Britain (GB) and Northern Ireland (NI)?	
Has access been limited to the appropriate intended audience? Is interaction with the social media activity limited or controlled, and if not how does this affect the risk of the activity?	
Is the audience expected to respond or participate in discussion?	
Is the role of the pharmaceutical company clear?	
How is the content reviewed, approved and maintained?	
What are the arrangements for pharmacovigilance obligations?	
Why could it not be considered as promotion to the public?	
Is it in line with company guidance? Is the company guidance clear and consistent with all applicable codes, laws and regulations?	



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