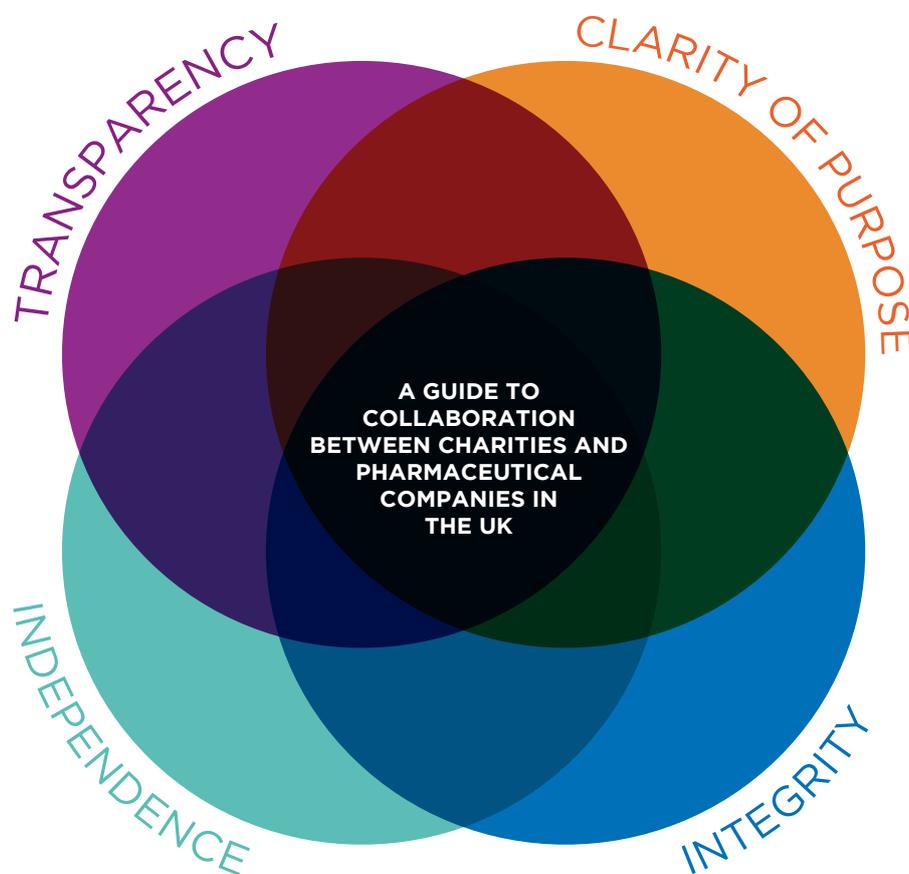




Working together, delivering for patients

A guide to collaboration between charities
and pharmaceutical companies in the UK



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THIS GUIDE IN SUMMARY

Collaboration in the interests of patients is a desirable goal, and can take many forms. This short guide is for charities¹ and pharmaceutical companies in the UK, to help them consider the key benefits, issues and risks that can arise when working together. The aim is to help ensure that collaborations work well for both parties and, ultimately, for patients².

This guide is not a code of conduct and has no binding force. It is intended to provide practical help, complementing other useful resources. It reflects consultation with a wide range of individuals and organisations.

This guide sets out the following principles for collaboration.

1. 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

2. INTEGRITY

Each party should act and be seen to act honestly and with integrity at all times

3. INDEPENDENCE

Each party should maintain their independence

4. 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

¹ Charities and other voluntary and civil society organisations with an interest in the health and wellbeing of different groups of patients, users of health and social care services, people living with particular conditions and disabilities, and their carers and families. The shorthand 'charity' fully includes the term 'patient organisation' used by the ABPI and the pharmaceutical industry but better captures the breadth and diversity of this sector.

² Throughout this document we use 'patients' as a shorthand for patients, users of health and social care services, people living with particular conditions and disabilities, and their carers and families.

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CONTEXT: WHY THIS GUIDE?

Many charities and pharmaceutical companies collaborate to achieve common objectives such as improving patient information or access to medicines.

Since collaboration brings both benefits and risks, and can be subject to critical scrutiny from third parties, guidance and direction are helpful and existing sources include the following:

- The charity regulators provide guidance to charities on collaborations and commercial partnerships, including [‘Choosing to Collaborate: Helping you to succeed’](#)³ and [‘Charities and Commercial Partners’](#)⁴.
- The Association of Medical Research Charities (AMRC) [‘An Essential Partnership: A guide for charities working with industry’](#)⁵ provides comprehensive guidance on collaborations between charities and companies for the purposes of research.
- The Association of the British Pharmaceutical Industry’s (ABPI) [Code of Practice](#) administered by the Prescription Medicines Code of Practice Authority (PMCPA). [Clause 27](#)⁶ of the ABPI Code of Practice contains detailed provisions for the pharmaceutical industry on relationships with patient organisations.

However, guidance has to date not covered the full range of relevant issues, addressed charities and industry together, or fully promoted mutual understanding. It was to fill these gaps that the ABPI and National Voices agreed to work together to produce this guide.

The interests of charities and pharmaceutical companies are distinct, but often overlap. For example, many charities have an interest in the development, launch and uptake of medicines, treatments and technologies that will help patients. For many charities, building relationships of various kinds with industry is an important part of fulfilling their charitable mission.

Pharmaceutical companies need to understand that patients and charities can provide relevant insight, intelligence and support. Companies and charities can work together on matters of common interest such as raising awareness of clinical trials and improving the measurement of patient outcomes following treatment.

³ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/409625/Choosing_to_collaborate.pdf

⁴ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284729/rs2text.pdf

⁵ <http://www.amrc.org.uk/publications/essential-partnership-principles-guidelines-working-industry>

⁶ <http://www.pmcpa.org.uk/Pages/default.aspx>

The principles in practice

1. CLARITY OF PURPOSE

Collaborations can take many forms, ranging from donations and working together, to the sharing of advice and expertise.

They can include, for example:

- campaigning and advocacy
- disease awareness campaigns
- events and meetings
- information and support for patients
- market research
- medical and scientific research projects
- policy publications and activity
- research and development
- training
- health technology assessments.

Collaboration needs to be based on mutual understanding and must be undertaken with care. Each party should be clear about both the benefits and risks of the collaboration. Focusing on the ultimate benefit for patients can help determine the purpose of the collaboration, and assess whether there is a sufficiently shared sense of purpose between the parties.

The parties should be able to:

- show that the collaboration is consistent with their respective organisational policies and aims
- demonstrate the link with the parties' respective missions, purposes and business aims
- understand each other's values, goals, priorities and limits.

It is important that both parties recognise and address any tensions, conflicts of interest or other issues that might make collaboration difficult, or impossible. For example, while collaboration need not involve financial transfers, some charities will not accept funding or other support from pharmaceutical companies as a matter of policy.

[Clause 27](#) of the ABPI Code of Practice contains detailed provisions for the pharmaceutical industry on relationships with patient organisations. These provisions do not prescribe what collaboration or partnership with a charity might look like, but are designed to ensure that pharmaceutical companies act ethically and respect the independence of charities. Individual companies may implement these provisions in different ways, whilst still complying with the Code.

Adherence to the ABPI [Code of Practice](#) is a condition of ABPI membership. Pharmaceutical companies do not need to be a member of the ABPI to abide by the Code although ABPI members produce 90% of the branded pharmaceuticals used by the NHS.

Many pharmaceutical companies that are not ABPI members choose to abide by the Code of Practice. Charities should ascertain the company's status and whether it abides by the ABPI Code of Practice. If it does not apply the Code there should be a discussion about which standards it does apply.

It is fundamental that a clear shared purpose and the scope of the collaboration are both captured in a written agreement or contract. The ABPI Code of Practice requires this. This will likely require preparatory work to ensure that the parties' expectations are aligned.

Neither party should enter into a contract if, following research and discussion, it has any concerns about the aims and objectives of the project. There is no shame in walking away from a potential agreement and doing so need not preclude working together on future collaborations.

Equally, parties should recognise that a contract agreed in good faith might later need to be terminated for various reasons. Contracts should contain termination clauses to cover such eventualities.

Working together, delivering for patients

A guide to collaboration between charities and pharmaceutical companies in the UK

2. INTEGRITY

Each party should act and be seen to act with honesty and integrity at all times. Each party should consider the integrity of the other, and whether collaboration will compromise its own integrity. Parties should not enter, or remain in, a collaboration which puts their integrity at risk.

Pharmaceutical companies will usually work to standard operating procedures (SOPs) and their own internal codes of business ethics. They also have to comply with relevant laws, such as [the Human Medicines Regulations 2012](#) and the [UK Bribery Act 2010](#).

Charities are bound by charity law and must comply with their governing documents. In particular, their activities must remain within the objects set out in the governing document. UK charities are regulated by their relevant charity regulator⁷ which is responsible for registering charities, ensuring legal compliance and, when necessary, taking enforcement action. The charity regulators provide guidance to charities on collaborations and commercial partnerships although current guidance does not directly address working with pharmaceutical companies.

Regulatory guidance⁸ to charities advises that, when partnering with a commercial organisation, a charity should take appropriate steps to protect its name and reputation and be wary of working with a company that has engaged in unethical trading. Charities are advised that before they enter into an agreement with any company they ascertain its financial state, its values and ethics and whether it has successfully worked with charities in the past.

In this context charities may wish to ascertain a company's policies and positions on various matters. For some charities, the disclosure of clinical trial results might be relevant, since this is important for assessing the benefits and risks of medicines. As the value of greater clinical trial disclosure is increasingly recognised, pharmaceutical companies are being urged to be more open with their data than is currently required and charities may wish to take account of a company's track record and position on the disclosure of clinical trial data in deciding whether or not to enter a collaboration.

⁷ In England and Wales this is the Charity Commission. The Scottish Charity Regulator and the Charity Commission for Northern Ireland cover the rest of the UK.

⁸ See Charity Commission guidance on working with companies and professional fundraisers: <https://www.gov.uk/charities-working-with-companies-and-professional-fundraisers> Though this guidance is in the context of fundraising, the principles apply more generally.

Working together, delivering for patients

A guide to collaboration between charities and pharmaceutical companies in the UK

3. INDEPENDENCE

It is vital for charities' integrity and reputation that they protect and maintain their independence from all funders, partners and collaborators. Pharmaceutical companies must also protect their reputation when entering into collaboration. When a charity collaborates with a pharmaceutical company, the independence of the charity is important for both parties.

Charities have a legal duty to act in accordance with their charitable objectives and need to ensure that these are not improperly influenced by funders and collaborators, whether these are pharmaceutical companies or other bodies.

The ABPI Code of Practice requires companies to respect the independence of patient organisations in a variety of ways. For example a company must not seek to influence a patient organisation's material in a manner favourable to its own commercial interests.

Clear governance and oversight are key to ensuring independence. Parties can take a number of measures, including:

- being clear about when collaborations require board or senior management sign off and/or notification
- considering setting an upper limit on the proportion of a charity's total income that can be contributed by any one party
- seeking, where possible, more than one funder or partner for a particular activity (the ABPI Code of Practice prevents companies requiring exclusivity by being the sole funder)
- ensuring a charity's editorial independence over materials, meetings and conference agendas etc., and ensuring clarity about intellectual property issues arising from the collaboration
- ensuring guidelines for the use of logos or description of medicines etc. are followed.

When a charity collaborates with a pharmaceutical company its independence can come under public and media scrutiny. Scrutiny might be increased if:

- a major proportion of a charity's funding comes from one or more pharmaceutical companies
- a charity advocates for regulatory approval or increased use of a particular treatment
- the charity and company collaborate to raise awareness of a particular condition, with the aim of increasing rates of diagnosis and treatment.

There is nothing necessarily improper about such situations, but they show the need for particular care and clarity about the relationship and the steps put in place to protect the charity's independence and the reputation of the pharmaceutical company. Each party should be prepared to be proactive in explaining its reasons for the collaboration.

Working together, delivering for patients

A guide to collaboration between charities and pharmaceutical companies in the UK

4. TRANSPARENCY

Transparency, including the disclosure of relationships, is vital for ensuring accountability, building trust and maintaining a good reputation. The digital age has multiplied the opportunities to be transparent and also increased the expectation of transparency.

- Companies are accountable to their shareholders (where applicable), staff and external stakeholders, and need to comply with the ABPI Code of Practice or their own policies and procedures.
- Charities are accountable to their members, beneficiaries and donors, as well as their regulator.

Each party should see it as part of normal business to be transparent about collaborations, the nature and purpose of the associated activities and the money or other support that is provided.

Not every organisation has to adopt exactly the same approach, but it should be as transparent as possible. For example, some charities would regard it as a necessary minimum to disclose the value, source and purpose of payment received (above a minimum level) and to ensure this information can be readily found in the charity's annual report, accounts and website.

Not only should parties consider reporting the value and source of funding but also, for the sake of transparency, both should ensure that funding is used only for the agreed purpose and any agreed additional activity outside of this is declared.

In considering what to disclose, charities should keep in mind not only direct financial transactions with companies but also help in kind from companies (which fall under the term 'transfers of value'), and support routed through third party intermediaries such as research and public affairs agencies.

The ABPI Code of Practice [Clause 27](#) requires companies to publish details about their relationships with patient organisations, to name the organisations, describe the nature of the activity (whether support or contracting for services) and the associated monetary and non-monetary values. The ABPI Code also encourages companies to include in their written contracts provisions regarding an obligation of the patient organisation to disclose any paid services they have provided to companies when they write or speak in public about a matter subject to the agreement or any other issue relating to that company.

Charities need to be aware of this requirement and ensure that the information they disclose about a particular collaboration is consistent with the company's own disclosure. Charities should be aware of the risk of appearing to have something to hide.

Charities should consider not only what to disclose but how to disclose it. The easier the information is to find, the less likely that someone will complain that the organisation has something to hide.

Working together, delivering for patients

A guide to collaboration between charities and pharmaceutical companies in the UK

USING THIS GUIDE: A CHECKLIST

- Has there been a frank discussion about the purpose and expected benefits of the collaboration, and any risks, addressing all the issues in this guide?
.....
 - Are the objectives and planned outcomes of the collaboration specified?
.....
 - Are the roles of each partner and reporting mechanisms specified?
.....
 - Has a written agreement or contract been put in place, which sets out how each party will adhere to the four key principles?
- Is there a named senior individual accountable for managing and maintaining the relationship and monitoring adherence to the four key principles?
.....
 - Is information about the collaboration published on the company and charity websites?
.....
 - Can each party confidently explain the collaboration in public?

WHAT NEXT?

We hope this guide offers help, reassurance and ideas to encourage successful collaboration between charities and companies.

We welcome comment and feedback on the guide, so that it can be updated regularly. We will also do our best to respond in a timely fashion if you wish to discuss these issues or seek further advice.

Please contact **National Voices** by email at info@nationalvoices.org.uk or on **020 3176 0738**

 **@NVTweeting**

Please contact the **ABPI** by email at abpicomms@abpi.org.uk or on **020 7930 3477**

 **@ABPI_UK**

If you have questions about the **ABPI Code of Practice** please contact the **PMCPA** via its website pmcpa.org.uk or on **020 7747 8880**

Working together, delivering for patients

A guide to collaboration between charities and pharmaceutical companies in the UK

HOW THIS GUIDE WAS PRODUCED

The project to produce this guide was launched in September 2014 as a joint initiative of the ABPI and National Voices.

The work was overseen by a steering group, chaired independently by Harry Cayton CBE, Chief Executive of the Professional Standards Authority and the former National Director for Patients and the Public at the Department of Health; he chaired the steering group in a personal capacity.

The steering group members were:

- **Mark Flannagan**, Chief Executive, Beating Bowel Cancer
- **Tony Sampson**, International Government Affairs Director, AbbVie
- **Sarah Vibert**, Acting Director of Strategy and External Affairs, Epilepsy Society
- **Dr Paul Schofield**, Medical Director, Napp Pharmaceuticals Limited.

The steering group was supported by officers of the ABPI and National Voices.

MD Healthcare was commissioned as project lead to consult relevant stakeholders and assemble material for the guide.

Key inputs were as follows:

- two workshops held on 5 November 2014 and 9 December 2014 to identify and discuss key issues for the guide. These were attended by more than 50 representatives from charities and the pharmaceutical industry
- an online survey completed by 31 charities and pharmaceutical companies
- structured interviews with more than 20 stakeholders, including representatives of the Medicines and Healthcare products Regulatory Agency, Care Quality Commission, Health Research Agency, NHS England, the Royal College of Physicians, the Faculty of Pharmaceutical Medicine, South London and Maudsley NHS Foundation Trust, and a number of charities and consultancies.

About the ABPI

The ABPI represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK.

Our industry, a major contributor to the economy of the UK, brings life-saving and life-enhancing medicines to patients. Our members supply 90 per cent of all medicines used by the NHS, and are researching and developing over two-thirds of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases.

The ABPI is recognised by government as the industry body negotiating on behalf of the branded pharmaceutical industry, for statutory consultation requirements including the pricing scheme for medicines in the UK.

About National Voices

National Voices is the coalition of health and social care charities in England. We work for a strong patient and citizen voice and services built around people. We stand up for voluntary organisations and their vital work for people's health and care.

We have more than 140 charity members and 20 professional and associate members. Our membership covers a diverse range of conditions and communities and connects with the experiences of millions of people.

