

Working with patients and patient organisations

A sourcebook for industry

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1 Introduction



The ABPI has produced this sourcebook to support pharmaceutical companies in working successfully and collaboratively with patients and patient organisations. We want to support relationships that are in the interests of patients and within the law and the ABPI Code. We also hope that the sourcebook will be helpful to patient organisations as they build partnerships with industry.

Many people have asked for a simple declaration that the ABPI, and its Code of Practice, support industry and patient organisations working together. The Introduction to the ABPI Code has always referred to this, and the 2019 edition, in the principles and overview of self-regulation, states that:

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

While this new sourcebook provides informal guidance, following it does not guarantee compliance. Companies need to ensure they comply with the ABPI Code.

This document has been prepared in response to suggestions from industry and patient organisations. There is a great deal of useful and thoughtful guidance available already from national and international organisations, in addition to the ABPI Code, and we are not seeking to replicate or replace what already exists. Rather, our aim in this sourcebook is to collate practical tools and tips and to provide pointers to sources of information.

The ideas you will find here constitute a framework for thinking and deciding on how best to engage with patient organisations. One size does not fit all, so inevitably there is not one template that can be applied to every situation. But we hope that you will find enough advice to help guide your way.

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

1 Introduction



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. We found there was a desire for some further guidance that could sit alongside the ABPI Code and help build alliances between industry and patient organisations.

We held workshops to define the topic areas and to look at some possible responses. We also carried out desk research to bring together available guides, and spoke to colleagues at the European Federation of Pharmaceutical Industries and Associations (EFPIA), and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).



Our working group initially identified five areas where further guidance would be of assistance:

- Definitions
- Events and meetings
- Research & development
- Product launches
- Payment
- A further area, that of principles and agreements, emerged from later workshops.

We have structured the sourcebook around these six areas.

About the ABPI Code of Practice

The ABPI Code of Practice sets standards for the promotion of medicines to health professionals and other relevant decision makers in the UK. It also covers interactions between the industry and health professionals. The ABPI Code sets standards relating to the provision of information about prescription-only medicines to the public and patients, and pharmaceutical companies' relationships with patient organisations. The ABPI Code does not cover the promotion of over-thecounter medicines to the public.

The ABPI Code is a self-regulatory code, first established by the ABPI in 1958. It is regularly updated and reviewed in consultation with 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).

1 Introduction



ABPI member companies agree to comply with the Code as a condition of membership, and in addition, about 60 non-member companies are signed up. The ABPI Code is administered by the Prescription Medicines Code of Practice Authority (PMCPA), which operates independently of the ABPI itself.

The ABPI Code demonstrates the commitment of the pharmaceutical industry to benefiting patients by operating 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.

The Introduction to the ABPI Code sets out the sanctions that may be applied if a company is found to have breached the ABPI Code.



2 Principles and agreements

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.

Here are some good questions to ask when setting up a new partnership:

- Why do I want to work with this organisation?
- How will patients ultimately benefit?
- How will I involve patients?
- What is the benefit to my organisation?
- Who decides on the scope of work?
- If everything was in the public domain, what would it look like?
- What money or benefits are involved?
- How will transparency be achieved?

The ABPI Code covers relationships with patient organisations in detail in Clause 27 and related supplementary information, including a checklist covering the minimum requirements for the written agreement that is required when a patient organisation works with a pharmaceutical company. The agreement must be certified, as set out in Clause 14.3.

The written agreement must include:

Name of the activity Names of the organisations involved (pharmaceutical companies, patient organisations and any third parties which will be brought in to help) Type of activity (e.g. unrestricted grant, specific meeting or publication etc.) Objectives Respective roles of the company and the patient organisation Time-frame Amount of funding Description of significant indirect/nonfinancial support (e.g. the donation of public relations agency time or free training courses) Statement that all parties are fully aware that sponsorship must be clearly acknowledged and apparent from the start Code or codes of practice that will apply Signatories to the agreement Date of the agreement



Bear in mind that while large patient organisations may be more familiar with agreements and have the resources to draft and scrutinise them, individuals or small organisations may not. Be careful that you are not excluding people or groups by insisting on an overly complex document – and use plain English. 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 are developing a guide to 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. To note, we are yet to see how the outputs from this work will align with the ABPI Code of Practice.

Note that a company cannot require that it is the sole funder or sponsor of a patient organisation. However, a patient organisation may choose, of its own will, to work with just one commercial organisation. The IFPMA explains this point in the Q&A in its 2019 Code (the ABPI Code incorporates the principles set out in the IFPMA Code):

What happens if only one pharmaceutical company wishes to support a particular patient organisation? Is this allowed?

Yes. Many patient organisations are supported by a number of pharmaceutical companies. There may, however, be situations where only one "It would be acceptable under the IFPMA Code to be the only pharmaceutical company providing funding as long as that company did not make its support conditional on it being the sole funder."

pharmaceutical company wishes to support a particular patient organisation or one of its activities. It would be acceptable under the IFPMA Code for that pharmaceutical company to be the only pharmaceutical company providing funding as long as that company did not make its support conditional on it being the sole funder.

Companies should bear in mind that commercial structures can be complicated for people outside the commercial world to navigate. Representatives of patient organisations may have very limited time or resources to devote to administration, so it is really helpful if the company can provide a consistent, single point of contact and take time to smooth the path.

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



Before settling on a definition, the Patients' Association recommends asking what is appropriate for a particular situation in its publication Working Together: An Essential Guide:

"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."

In other words, avoid assumptions. It may also be true that a person or group will have a different definition depending on the role they are taking in a particular activity or have overlapping responsibilities.

Consider these questions:

- 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 or use the information I receive?

Definitions will have an impact on what information you can provide to someone and how you can work with them. For example, you should be aware that the ABPI Code states that "prescription only medicines must not be advertised to the public" (Clause 26.1), reflecting UK regulations relating to advertising – and the public includes patients, of course. The ABPI Code provides a series of definitions in Clause 1 for health professionals, other relevant decision makers and healthcare organisations.

ABPI Code – Clause 1

1.4

The term "health professional" includes members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine.

1.5

The term "other relevant decision makers" particularly includes those with an NHS role who could influence the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not health professionals.

1.9

The term "healthcare organisation" means either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more health professionals or other relevant decision makers provide services.

3 Definitions

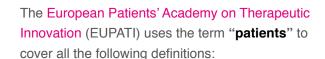


The ABPI Code defines who is covered by Clause 27 on relationships with **patient organisations**:

"27.1 Pharmaceutical companies can interact with patient organisations or any user organisation such as disability organisations, carer or relative organisations and consumer organisations to support their work, including assistance in the provision of appropriate information to the public, patients and carers."

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

"Patient organisations are defined as not-for-profit organisations (including the umbrella organisations to which they belong), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers."



- "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.

Some people prefer the term "people affected by" or "consumer" in place of the word patient.

3 Definitions



How do "expert patients" differ from patients?

Legally, there is no difference. So how and why would you make a distinction? It depends what you want to do. A patient who has participated in many events, for example, may be able to give useful feedback on the quality of a conference or best practice in patient involvement. Another consideration is what information you might want to share, and how you would want to share it (see p11 below).

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. More informal, subjective 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.

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:

Experiential and academic skills that define expert patients:

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 patients' associations	Responsibilities in patients' 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

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

4 Events and meetings



The ABPI considers that working with patients and patient organisations can bring significant public health benefits. At conferences, congresses, clinical trial days and other events, patients and representatives of patient organisations can add personal experience and a welcome perspective.

What the Code says

The ABPI Code states that "The requirements of Clause 22, which covers meetings for health professionals and other relevant decision makers, also apply to pharmaceutical companies supporting patient organisation meetings."

"...in the case of clear health needs such as disability, companies can pay for subsistence, accommodation, genuine registration fees and reasonable travel costs for an accompanying carer."



Clause 22 provides detail on what is considered appropriate. There are some clear principles set out in the supplementary information, extracted below:

- The venue must be appropriate and conducive to the main purpose of the meeting; lavish, extravagant or deluxe venues must not be used, companies must not sponsor or organise entertainment (such as sporting or leisure events) and companies should avoid using venues that are renowned for their entertainment facilities.
- The meeting must have a clear educational content.
- The subsistence associated with the meeting must be secondary to the nature of the meeting, must be appropriate and not out of proportion to the occasion.
- Any hospitality provided must not extend to a spouse or other such person unless that person is a health professional or other relevant decision maker and gualifies as a proper delegate or participant at the meeting in their own right.
- Spouses and other accompanying persons, unless qualified as above, may not attend the actual meeting and may not receive any associated hospitality at the company's expense; the entire costs which their presence involves are the responsibility of those they accompany.

Note that the supplementary information to Clause 27 makes it clear that companies can pay for carers' expenses under certain conditions:

"...in the case of clear health needs such as disability, companies can pay for subsistence, accommodation, genuine registration fees and reasonable travel costs for an accompanying carer."

4 Events and meetings



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 indeed patient organisations – worry about what can be shared when patients are in the room.

The principle on sharing information with the general public still stands: promotion of prescription-only medicines is not permitted. That means that promotional presentations or other material suitable for health professionals would not be appropriate for patients to see. Clause 26.2 of the ABPI Code, and associated supplementary information, provides detail on information that can be shared with the public.

But people can find it irritating to have to leave a platform just when the debate is getting interesting; it can seem very strange to have to walk past posters or other material that is covered up because it is not for them.

When planning ahead, think carefully about room layout and access, structure of the agenda, timing of Q&As or closing remarks, and how to signpost clearly in advance which sessions are suitable for which audiences; with webinars or other online events, descriptive language and passwords will help to make this distinction. If it's an independent congress, provide feedback on the format ahead of time.

It is useful to explain to a patient participant the reasons why certain aspects are not suitable for patients, rather than just saying no.

As for any activity, the purpose of patient or patient organisation involvement at an event should be articulated well before it happens, 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 as well as the need for good compliance.

This also means considering inclusion requirements in terms of venue, as far as reasonably possible, and 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. You can find further information on NIHR INVOLVE's diversity and inclusion pages, including guidance on working with children and young people.





Overseas events

There have to be valid reasons for using a venue outside the UK for a meeting, which are set out in the supplementary information to Clause 22:

- Most of the invitees are from outside the UK, and given their country of origin it makes greater logistical sense to hold the meeting outside the UK; or
- The relevant resource or expertise that is the subject of the meeting is outside the UK.

As with any meeting, consider carefully the principles of Clause 22, set out above.

The same rules apply for overseas events as for UK events, in terms of what can be paid to individuals and how this is disclosed. As for any activity, the purpose of patient or patient organisation at an event should be articulated well before it happens.



4 Events and meetings



Advisory boards

Companies can arrange advisory board meetings and pay health professionals and others – for example patients or representatives of patient organisations – for advice on subjects relevant to their products.

Advisory boards are not used to promote a company's medicines and must not be an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. They should only be held to enable companies to answer legitimate business questions to which they do not already know the answer.

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", you should stop and think carefully in case there is a compliance issue.

Advisory boards are not used to promote a company's medicines and must not be an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. They should only be held to enable companies to answer legitimate business questions to which they do not already know the answer.

- 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 limited so as 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 the participants being paid no more than 'fair market value'?
- Are intended presentations to participants relevant to their role in answering the business question?
- Is this the only advisory board to address the business question at issue?
- Are the participants expected to do any preparatory work?
- Are all those involved with the meeting (staff, third parties, participants) clear on the need for and expected output from the meeting?

4 Events and meetings



Here are some other points to consider:

- 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 e.g. a 12 month period? If so, what is the justification for another one?
- What follow-up, if any, is to be undertaken with participants? If so, is this appropriate given the non-promotional nature of advisory boards?
- Is this advisory board held in conjunction with any other meeting such as a learned society congress?



5 Research and development



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 Research's INVOLVE initiative explains more about public involvement in research and features some practical tools and resources for researchers and others on its website.

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 lifecycle 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.

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 of the ABPI Code.

As with any activity, transparency is vital in building and supporting trust. Clause 13 of the ABPI Code covers clinical trials and non-interventional studies of marketed medicines and sets out the requirements for disclosure.

"... 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."

6 Product launches



Many companies think about 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 all the same guidelines and rules, 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 shared reactively is not promotional, or for a promotional purpose. (See Clause 26.2 of the ABPI Code for more detail).



7 Payment



The ABPI supports collaboration between industry and patients, and patient organisations, in the interests of enhancing public health. In practical terms, this means that people will need to devote time to participate in activities with industry. They can be paid or recognised in other ways for the value they bring and the effort they make.

As the EFPIA guide Working Together with Patient Groups states, irrespective of the strong rationale for engagement, any relationship between patient organisations and the pharmaceutical industry can be perceived as commercially motivated. That's why it is crucial to stick to practices of clarity, integrity, independence, transparency and non-interference.

Building on the EFPIA guide, the EFPIA Patient Think-Tank (PTT) has been requested to provide further guidance (non-legally binding and complementary to the EFPIA Code) on remuneration of patients, patient organisation representatives and carers for work undertaken with pharmaceutical companies and associations. The PTT is establishing a set of principles, also suggesting objective criteria based on which the level of remuneration can be determined. The principles are being co-created by representatives of patient organisations and the researchbased pharmaceutical industry through the PTT in collaboration with the EFPIA Ethics and Compliance Committee, WECAN and Patient Focused Medicines Development (PFMD).

It is important to state that while these highlevel principles can shape thinking, all payment decisions including when to pay and how much are the responsibility of individual companies. National Voices has a policy of supporting unfunded individuals with lived experience who contribute to their events. Remember that they may need to declare payments for tax, and there might be an impact on benefits.

What the ABPI Code says

In this area, the Code focuses on the importance of transparency and having written agreements.

Under Clause 27, companies must make publicly available each year a list of the patient organisations to which they provide support (both financial and significant non-financial), with a description of what that support is for, and the monetary value. Agreements should include the amount of funding, as noted above.

Compensation should be reasonable and not exceed the fair market value of the services provided.

It is crucial to stick to practices of clarity, integrity, independence, transparency and non-interference.

7 Payment



But what is fair market value?

"Fair market value" is not defined in the ABPI Code; the ABPI cannot recommend rates due to competition law. It 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 companies will take their own approach, patients value consistency and clarity on the reasons behind it. Remember that reimbursement of expenses is not the same as compensation.

NIHR INVOLVE 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.

The Change Foundation, an Ontario-based policy think tank, has a useful decision tool on its website as well as a brief summary of things to think about when considering compensation.

"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.

8 Conclusion



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

While the core principles of behaviour should remain fairly constant, this is a developing area with new information and updates continuing to emerge. We will aim to update the sourcebook regularly and would appreciate any comments and feedback.

As a reminder, while this new sourcebook provides informal guidance, following it does not guarantee compliance. Companies need to ensure they comply with the ABPI Code.



9 APPENDIX: Further information and sources



ABPI:

Code of Practice

ABPI/National Voices:

Working Together, Delivering For Patients

Association of Medical Research Charities:

An Essential Partnership: A guide for charities working with industry

EFPIA:

Working Together with Patient Groups

EFPIA:

Health Collaboration Guide 2017

IFPMA:

Code of Practice 2019

Patient Focused Medicines Development, Workgroup of European Patient Advocacy Networks, Myeloma Patients Europe:

Reasonable Agreements between Patient Advocates and Pharmaceutical Companies European Patients' Academy on Therapeutic Innovation

Patients' Association

Plain English Campaign

European Respiratory Journal:

The Expert Patient: towards a novel definition

National Institute for Health Research INVOLVE

Innovative Medicines Initiative:

PARADIGM

Change Foundation:

Should Money Come Into It?



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Napp	Diabetes UK	
Novo Nordisk	Haemophilia UK	
Sanofi	Heart Rhythm Alliance	
Sunovion	Kidney Research UK	
Teva	MPS Society	
UCB	MS Society	
EFPIA	National Voices	
	NCRI	
	NIHR INVOLVE	
	Pain UK	

Parkinsons UK

Primary Care Rheumatology & Musculoskeletal Medicine Society

UK Gout Society



11 How to get in touch



ABPI:

ABPI Head Office 7th floor, Southside 105 Victoria Street London SW1E 6QT

Telephone: +44 (0) 20 7930 3477 Email: getintouch@abpi.org.uk www.apbi.org.uk https://twitter.com/ABPI_UK

PMCPA:

7th floor, Southside 105 Victoria Street London SW1E 6QT

Telephone: +44 (0) 7747 8880 www.pmcpa.org.uk https://twitter.com/PMCPAUK

Complaints should be submitted to the Director of the PMCPA at the above address, email complaints@pmcpa.org.uk.



The Association of the British Pharmaceutical Industry

A company limited by guarantee registered in England & Wales number 09826787

Registered office 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT

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