

Leukaemia CARE Code of Practice

This Code of Conduct governing corporate funding is a commitment undertaken by Leukaemia CARE regarding our financial relationships with commercial entities and the pharmaceutical industry particularly. This Code of Conduct Governing Corporate Funding will come into effect on April 1st, 2013 and is intended to minimise the impact of real, potential or perceived conflict of interest that may arise when patient organisations accept financial support from companies.

Guiding Principles

The Code was developed based on the following guiding principles:

- Patient Interests; all activities of Leukaemia CARE will be conducted in accordance with the best interests of patients, and of Leukaemia CARE.
- Integrity and Scrutiny; Leukaemia CARE shall perform its duties in a manner that will withstand public scrutiny.
- Respect; Leukaemia CARE will respect the stakeholder relations policies of the companies with which they are involved.
- Impartiality and Transparency; Leukaemia CARE should ensure that it is impartial and objective and decisions are made on the basis of merit. We will be as open as possible about all actions that we take and any advice that we may provide.
- Accountability; Leukaemia CARE accepts accountability for our compliance with the Code and ensure that our sponsors are familiar with the Code.

Leukaemia CARE Code of Conduct Governing Corporate Funding

The Leukaemia CARE Code of Conduct Governing Corporate Funding (the Code) is a commitment undertaken by Leukaemia CARE, to adhere to specific policies regarding our financial relationships with commercial entities. The Code is intended to minimise the impact of real, potential or perceived conflict of interest that may arise when we as a patient organisation accept financial support from companies in general and members of the pharmaceutical industry in particular.

Definitions

The following definitions apply to terms used throughout the Code:

'Company' refers to a commercial entity providing, or seeking to provide, funding to Leukaemia CARE. This definition includes agents of the company. The term is also used in the collective sense where more than one company is involved in a particular undertaking.

'Funding' refers to any of the five categories of financial support outlined under the policies section Guiding Principles. The Code of Conduct Governing Corporate Funding is based on the following guiding principles:

- *Patient Interests*: all activities of Leukaemia CARE will be conducted in accordance with the best interests of patients as a whole.
- *Integrity and Scrutiny*: Leukaemia CARE shall perform its duty in a manner that will withstand public scrutiny.
- *Respect*: Leukaemia CARE will respect the stakeholder relations policies of the companies with which they are involved.
- *Impartiality and Transparency*: Leukaemia CARE should ensure that it is impartial and objective and that decisions are made on the basis of merit. We will be as open as possible about all actions that we take and advice that they provide.
- *Accountability*: Leukaemia CARE accepts accountability for our compliance with the Code and will ensure that our sponsors are familiar with the Code Policies.

Conflicts of interest

Conflicts of interest may arise in a mutual relationship where one party has the capacity to exert undue influence over another. The following policies have been developed to ensure that relationships of Leukaemia CARE and our corporate funders are ethical, transparent and reflect positively on both organisations.

Funding: Categories

Five funding categories are included in the Code:

a) Project funding - where Leukaemia CARE establishes a collaborative partnership with a company to undertake a project relating to an issue of mutual interest. The following features will apply to this relationship:

i) Leukaemia CARE maintains editorial control over all materials produced in connection with the project.

ii) The company may have representation on the project steering committee; however decisions about the composition of the project steering committee are at the sole discretion of Leukaemia CARE.

iii) The sponsor will be acknowledged, in a way that is agreed in negotiations with the company.

iv) Leukaemia CARE will not endorse or promote individual products or services.

v) Leukaemia CARE and the company may both benefit from the relationship.

b) Sponsorship - where a company funds a single activity such as an external meeting or newsletter. In this case the following will apply:

i) The company has no involvement in the activity for which the sponsorship is granted.

ii) Leukaemia CARE maintains editorial control over all materials or meeting programs and has sole discretion on the meeting attendees.

iii) Leukaemia CARE will not endorse or promote the company's products or services.

iv) The sponsor will be acknowledged, in a way that is agreed in negotiations with the company.

v) Leukaemia CARE and the company may both benefit from the relationship.

c) Unrestricted grants are defined where all of the following apply:

i) The company has no involvement in the project for which the grant is used.

ii) The grant will be acknowledged, however the company's logo is not used.

iii) Leukaemia CARE controls the wording and position of the credit.

d) Financial donations and in-kind support may be offered to Leukaemia CARE.

i) In these cases Leukaemia CARE will acknowledge the name of the corporate donor on our website and/or annual report if the amount of support is greater than 10 per cent of our total annual revenues. The monetary value of in-kind support over £1,000 should be included in the total amount of the sponsorship.

e) Support of research activities – (Under normal circumstances Leukaemia CARE does not get involved with research, particularly clinical or medical research, but on occasions we have been involved in research that explores quality of life aspects of patients or carers

affected by a diagnosis of blood cancer. Under those circumstances the following conditions will apply:

i) Financial support for research projects may be provided by a company for administration by Leukaemia CARE. This may take the form of an unrestricted grant or project funding and the respective policies apply to each form of support.

ii) The company may have representation on the project steering committee; however Leukaemia CARE maintains control over the choice of research organisation, study design and publication of results.

iii) The sponsor(s) of any research activities will be acknowledged at the presentation and publication of results.

Guiding Principles

Leukaemia CARE agrees to adhere to the following policies when accepting project funding, sponsorship, grants or donations from companies.

i) Before accepting funding from a company, Leukaemia CARE's director(s) (and depending on the nature of the funding, the trustees) must conduct sufficient due diligence to satisfy itself that:

- There is strong reason to believe that the donation, grant or sponsorship will result in benefit to Leukaemia CARE and to the patients it serves.
- The company's type of business, its corporate governance policies and its reputation in working with patient organisations do not present any cause for concern.
- Leukaemia CARE will not knowingly accept any type of funding from a company that produces or sells commercial tobacco products or receives funding from their sales.

ii) Leukaemia CARE will maintain its independence of action.

- The content of communications originating from Leukaemia CARE, such as patient submissions for drug reviews, policy submissions, and information for patients and the public, newsletters and presentations must be developed entirely by Leukaemia CARE without any assistance from the staff of companies or their agencies.
- Submissions for drug reviews or policy recommendations will not be shared or reviewed with sponsors in advance.
- Leukaemia CARE will not endorse or promote individual products or services.
- Advocacy activities, such as making patient submissions for drug reviews or petitioning governments to fund a particular drug, are not considered promotion because these activities are intended to improve access to the treatment, rather than recommend that it be prescribed. Similarly, providing educational information on available treatments is not considered promotion.

- If a company makes any attempt to coerce Leukaemia CARE to conform to its marketing agenda, either explicitly or implicitly, or does not conform to the memorandum of agreement, Leukaemia CARE will reject the funds or terminate any on-going project.

iii) Leukaemia CARE will maintain mutually respectful and transparent relations.

- Leukaemia CARE will sign a written agreement with all companies outlining each partner's contribution and responsibilities. The company and Leukaemia CARE must agree to abide by each other's codes of conduct.
- A sponsor's support will be acknowledged transparently and in an appropriate way following discussions with the company concerned.

iv) Leukaemia CARE will proactively limit the possibility of influence.

- Leukaemia CARE should seek a diversity of funding sources and should not allow any one corporate sponsor to contribute more than five per cent of their total revenues for the year, including the value of in-kind services.

v) Policies for Companies

Leukaemia CARE will not embark upon or continue with any sponsorship, grant making or collaborative venture that might damage its reputation or result in the dissemination of biased and inaccurate information. Therefore, when working with Leukaemia CARE, companies are expected to adhere to the following guidelines:

- Leukaemia CARE must be consulted whenever and wherever its name is used, particularly in external communications. Approval must be sought for any copy produced which refers to an initiative of Leukaemia CARE that is supported by the company.
- At no time can Leukaemia CARE's logo be used without express written permission.
- At no time can press releases be issued which refer to Leukaemia CARE without Leukaemia CARE's prior approval. Likewise, suggested quotes can be prepared but must always be agreed by an appropriate person of authority within Leukaemia CARE.
- Leukaemia CARE retains a veto over all materials produced in connection with an initiative. Adequate approval time needs to be allowed for this as it may require approval from one or more of the directors, (or trustees, depending on the nature of the decision).

vi) Where more than one branded version of a product exists, any materials produced as part of an initiative will use either the scientific name or several different brand names.

Commitment and Enforcement

Commitment to the Code will be overseen by the officers and trustees of Leukaemia CARE, and adherence to the Code will be expected from all members of Leukaemia CARE, whether

they are employed full-time or part-time, or volunteers; and all members are accountable for enforcing these policies.

This Code will be published in full on our website, along with the names of those organisations from whom we have had support, and from whom we are currently receiving support.

Questions & Answers

Q1: why was the Code developed?

A: The Code was developed to demonstrate the commitment of Leukaemia CARE to adhere to consistent and transparent policies regarding corporate funding. As Leukaemia CARE works to strengthen the patient voice in areas such as drug review processes, it is essential that Leukaemia CARE is recognised as being a credible, independent source of information and opinion.

Q2: How does the Code help to establish the credibility of Leukaemia CARE?

A: The Code helps to achieve three main objectives:

1. To support Leukaemia CARE in asserting and maintaining our independence from commercial influences.
2. To clarify the position of Leukaemia CARE to entities with whom we have business relationships, and to the wider public.
3. Having a consistent code of conduct is becoming standard practice for patient organisations worldwide; indeed this Code was modelled after established patient organisation codes in Europe and around the world. Leukaemia CARE frequently makes submissions to several Health Technology Appraisals groups in the UK; The National Institute for Health and Clinical Excellence (NICE); Scottish Medicines Consortium (SMC) and the All Wales Medicines Strategy Group (AWMSG), and this Code will enable us to do so to the same level of visibility, transparency and ethical conduct as other participants in the these processes.

Q3: How was this Code developed?

A: This version of the Code (Leukaemia CARE's) - was developed from a Code developed by the Canadian Cancer Action Network (CCAN) in response to concerns expressed by the pan-Canadian Oncology Drug Review (pCODR) and other stakeholders (Ontario Public Drug Programs (OPDP), Canadian Agency for Drugs and Technologies in Health (CADTH)) about the financial relationships between patient groups making submissions to the review process and the companies that manufacture the drugs under review.

The Code was based on that of the European Cancer Patient Coalition (ECPC). It was also informed by: the codes of the International Association of Patient Organizations (IAPO) and the Canadian Cancer Society; the requirements of drug review processes across Canada (pCODR, Ontario Public Drug Programs, BC Pharmacare, Canadian Agency for Drugs and Technologies in Health (CADTH)); and the pharmaceutical industry association (Rx&D) guidelines on stakeholder relationships.

Q4: The Code specifies that patient organisations must not promote a product; however a big part of our organisation's activities is advocacy for new drugs. Also, for some cancers there is only one drug treatment, so we cannot avoid speaking about the value of a specific medication.

A: "Promotion" is defined as endorsing a specific brand-name product. A patient organisation that promotes a product lends its own credibility and the trust of its constituents to the brand. As a result, patients may be more likely to consider using the product. Situations where patient organisations are in a position to potentially promote a product are:

- a) Recognising the financial contributions of a corporate funder
- b) Providing product information intended for patients and the public (on a website or in a brochure, for example)
- c) Advocating for a particular drug to be approved or funded
- d) Corporate recognition

Funders of projects (sponsorships) are recognised at the corporate and not the product level. For example, the patient organisation and the funder may agree to place the company's corporate logo on signage for a meeting, or on a brochure produced with the funds provided. However, the appearance of a product logo would constitute promotion.

- b) Product information

An important role of patient organisations is to raise awareness about new treatment options (which may include specific drugs or other technologies) and to provide factual and balanced information on the place of a new treatment in therapy. Patient organisations are not in a position to recommend a specific treatment to a patient or to suggest that one treatment is preferable to others.

To reduce the perception of promotion, patient organisations are encouraged to communicate information about all new drugs and other forms of treatment in a consistent and objective manner. Also, the organisation may wish to include a disclaimer on their website to the effect that the information is provided for educational purposes only and that patients should speak to their doctor about treatment options.

c) Advocacy

Advocacy activities, such as making patient submissions for drug reviews or petitioning governments to fund a particular drug, are not considered promotion because these activities are intended to improve access to the treatment, rather than recommend that it be prescribed. Information presented by patient organisations objectively communicates the value that patients place on the specific treatment, from their own perspectives, compared to standard treatment regimens.

Many patient organisations appeal to the news media to garner public attention to the need for approval or funding of a particular treatment. To avoid being promotional, messages intended for the news media should speak to the need for access to the treatment and its potential value to a patient population, but should not recommend a specific treatment. For example, “we advocate that the government funds Drug A, because it has been proven to be a potentially valuable treatment option for patients with cancer B. We believe that oncologists should be able to prescribe this medication for all patients who may benefit.” In contrast, a promotional statement would be: “We advocate that the government funds Drug A, because we believe it is the best option for patients with cancer B.”

To ensure that patient submissions and other advocacy activities are not perceived as being promotional, the following guidelines should be followed. Information presented to drug review bodies should be presented as:

- i) Based on evidence and not opinion
- ii) Representative of the experiences and perspectives of as broad a patient population as possible
- iii) Addressing topics that are relevant to the review process
- iv) Drugs and other technologies should be referred to by their class whenever possible (for example, all drugs with the same mechanism of action, all diagnostic procedures or surgical treatments using the same technology). If a specific product is mentioned, its generic name should be used first, followed by the brand name. The intent of including the brand name is

to make the communication clearer and this usage does not connote promotion of a particular product.