CHARITY COMMISSION
FOR ENGLAND AND WALES

Operational Guidance (OG) 304 Complementary and Alternative Medicine

Overview

The Commission recognises that many complementary medicine and alternative medicine (referred to in this guidance as '**CAM**') therapies may give help and comfort to people seeking to promote their health, relieve sickness, alleviate a medical condition or relieve suffering.

Registration of a charity is acceptance that the organisation meets the legal test for being a charity, including that it is established for exclusively charitable purposes for the public benefit. Public benefit is based on evidence. In registering a CAM organisation as a charity we are not endorsing any treatment or confirming its efficacy but confirming it meets the test for charitable status including that of benefit.

This guidance is to assist Commission staff in establishing whether organisations with purposes which rely on the use or promotion of CAM therapies are charities, and replaces the previous guidance issued.

Benefit may arise, for example in palliative relief, even where scientific efficacy of a medical effect has not been established. Where the claimed benefit extends to the cure or treatment of a particular condition or illness then it remains necessary to establish efficacy in relation to the specific condition.

The fact that a charity, or an applicant for registration, uses CAM therapies as part of its work does not necessarily bring it within the scope of this guidance. This guidance relates to organisations with purposes which rely on the use or promotion of such therapies – i.e. where this is an essential element of the organisation's purposes. This is what we mean in this guidance by the term "CAM organisation".

We refer in this guidance to evidence of claimed benefit rather than efficacy of treatment. We do so to reflect the requirement for public benefit to be evidenced and to recognise the range of ways in which CAM may support charitable purposes.

The very nature of diagnosing, treating or curing illness and disease, or alleviating the suffering of those who are ill, may involve considerable risk of harm - for example, as a result of misdiagnosis or wrong or inadequate treatment. So when we consider an application to register as a charity an organisation promoting CAM, we must carefully assess the nature and cogency of evidence to support the claimed benefits against any potential harm.

Summary of the guidance

This guidance is intended to help caseworkers make decisions about whether organisations with purposes which rely on the use or promotion of CAM therapies have aims which fall within the list of descriptions of purposes in the Charities Act 2011, and are for the public benefit.

In many cases, purposes which rely on the use or promotion of CAM therapies will be purposes which are argued to fall within s3(1)(d) of the 2011 Act, the 'advancement of health or the saving of lives'

(which includes the prevention or relief of sickness, disease or human suffering and the promotion of health). However, the use of CAM therapies may form part of other purposes, including purposes which may relate to the relief of need, the advancement of religion, the advancement of education or promotion of animal welfare but which do not form part of this guidance, in which case the same principles may apply.

This guidance relates to purposes which are to be furthered through the use or promotion of CAM therapies – that is, purposes which rely on the CAM therapy having a particular beneficial effect.

It explains:

- the essential information we need (section 2)
- the requirement to evidence the benefit (section 5.1)
- sources of evidence to help identify the claimed benefit (section 5.2)
- the types of evidence available and assessing the evidence (section 5.3)
- forms of subjective evidence based on patient reporting (section 5.6)
- how to assess the impact of any potential for harm and how this affects public benefit in order to make the decision (section 7)

Casework Guidance

Key points

When considering applications for registration as a charity from organisations using CAM to fulfil their purposes we need to identify:

- the purposes of the organisation - what the purposes are and whether they fall within the descriptions of purposes in the Charities Act 2011
- whether the purpose is for the public benefit. (This guidance deals only with consideration of the 'benefit' aspect of public benefit. Caseworkers will still need to consider whether the 'public' aspect has been demonstrated)

This means identifying what CAM is being used or promoted. In each case we take an evidence-based approach to identify:

- what the benefits are - is the proposed purpose capable of fulfilling the benefits claimed for it? In each case the evidence must be appropriate to the claim made. See section 5 for more information about the evidence we need to consider an application
- any potential harm from use of the therapy and being satisfied that the harm does not outweigh the benefits. See sections 5.4 and 7 for more information on how we assess this

1. Key terms you need to understand when considering CAM cases

'CAM' is shorthand for 'complementary and alternative medicine'. The Commission uses this phrase to refer to any form of therapy which does not form part of conventional medicine.

'Complementary' medicine is offered alongside conventional medicine (i.e. to complement it). It is not intended as a substitute for conventional medicine.

'Alternative' medicine is offered separately from (i.e. as an alternative to) conventional medicine. It may be offered both alongside and instead of conventional medicine.

The same therapy might be offered as a complementary or alternative method, depending on the circumstances of the particular organisation. However, where a method is intended to be used as a complementary method we would expect an organisation to use it for this purpose and not as an alternative to conventional medicine. If this was found to be the case in respect of an existing registered charity then further regulatory assessment and action may be needed.

In this guidance, when we use the term 'therapy' this includes any form of therapy, treatment, medication, supplement or other practice which is intended to diagnose, alleviate, cure or relieve any medical condition, or otherwise to further any charitable purpose by its promotion or application.

When we use the term 'palliative' this refers to the relief of suffering, whether or not this is provided in the context of terminal illness.

2. Essential information we need in order to determine all CAM applications

In considering any application for charity registration from an organisation with purposes which rely upon the use or promotion of CAM, we need the following information to determine whether it meets the test for charitable status:

To identify purpose:

- the charitable purpose or purposes that the organisation is seeking to carry out by the use or promotion of CAM. This is to be assessed in line with our usual approach to identifying purposes in the context of charitable status

To identify benefit:

- the particular therapy used by the proposed charity to carry out its purposes, and how it will provide a benefit, such as the particular charitable need that it is intended to relieve
- whether the therapy will be used to diagnose, relieve or cure a condition, or to relieve the suffering of those with a particular condition
- whether it will be provided as a complementary or alternative method
- the full extent of the claims made by the promoters about the benefits that recipients will gain
- evidence (where necessary) of the benefit claimed

We may also want to consider the scope of the proposed or potential beneficiaries.

See section 5 for more information about what we mean by evidence.

To consider the potential for harm:

- evidence (if necessary) that any potential for harm is reduced so that the harm does not outweigh the benefit. See section 7.2 for information on what evidence we expect applicants to provide to show this

A note about public and private benefit

This guidance sets out criteria for assessing the 'benefit' aspect of public benefit. We also need to consider whether there are any factors that impact on the 'public' aspect. An issue that can arise for organisations promoting CAM is personal benefit - where, for instance, trustees are used as practitioners of the method being used. Caseworkers should follow the approach set out in our public benefit guidance when considering issues around personal benefit.

3. Our approach when considering applications from organisations with purposes which rely on the use or promotion of CAM

To be established as a charity an organisation must have a purpose which falls within the description of purposes and is for the public benefit.

Where the purpose necessarily relies on an activity, such as the use of a therapy, it is necessary to demonstrate that the activity, which forms part of the purpose, does genuinely further the purpose, for the public benefit.

We take an evidence-based approach in considering the claimed benefits and the evidence which exists to support the claims.

In considering the claimed benefit it is necessary to consider specifically whether the claimed benefit relates to a specific illness or symptoms or is claimed to provide a generic benefit in respect of suffering and if so how. In either case evidence will be required to establish the benefit.

In identifying the claimed benefit we would seek to distinguish between:

- Curative – that the therapy is capable of curing the illness or condition being treated
- Diagnostic – that the therapy is capable of diagnosing illness or conditions
- Palliative – that the therapy does not cure or diagnose but provides relief from symptoms of illness or condition. This may include relief from the effects of conventional treatment

To establish that a purpose is for public benefit:

- the particular therapy must be shown to be capable of curing, diagnosing or providing palliative relief in respect of any particular illnesses or conditions according to the claims made by the organisation seeking registration (see section 5)

- the therapy must be shown to be capable of being delivered safely and effectively for the public benefit, with any potential harm minimised or reduced so that the risk of harm does not outweigh the benefits (see section 7)

4. CAM and purposes which are capable of being charitable

How do we identify a 'CAM organisation'?

A CAM organisation will not necessarily identify itself in those terms. However, the information provided by an applicant about what the organisation is set up to achieve will indicate whether its purposes rely on the use or promotion of CAM. Case officers dealing with applications from CAM organisations should refer in correspondence to this guidance as being relevant to an application.

An organisation using CAM to achieve its purposes may have purposes falling within s3(1)(d) of the Charities Act 2011 - the advancement of health or saving of lives.

Other purpose descriptions that may apply are:

- s3(1)(b) – the advancement of education (e.g. where carrying on research for public benefit)
- s3(1)(c) – the advancement of religion
- s3(1)(j) – relief in need on grounds of ill-health (for instance where addressing a specific health need)
- s3(1)(k) – the advancement of animal welfare

When considering applications from CAM organisations we apply the same criteria as for any other organisation established for similar purposes.

Taken together, the information referred to in section 2 will help caseworkers identify which charitable purpose is being furthered through the provision of the CAM therapy in question and therefore what the organisation needs to demonstrate in its application.

For more information about the descriptions of charitable purposes and the characteristics that need to be met, see our guidance on the descriptions of charitable purposes.

Additional information can also be found in our guidance on Public Benefit.

5. Evidence of claimed benefit of a CAM method and what information we need to consider

When assessing whether a CAM method as used by the applicant organisation is capable of fulfilling the claims made for it, we will look for the best available evidence that the method being used provides benefits according to those claims. In all cases we need to consider the available evidence as a whole.

Objective, scientifically-based evidence will be required for any claims to cure medical conditions. Where the benefit claimed is palliative (relieving suffering), it may be possible to establish benefit without evidence of a physiological effect. In those cases, patient reporting evidence, of appropriate quality, may be sufficient to establish claimed benefit.

5.1 Evidential Requirement

- a purpose must satisfy both the public and benefit aspects of public benefit
- it is a matter for the Court or the Commission to determine on the evidence before it if the requirement is satisfied

- benefit may be sufficiently obvious that it is not necessary to require further evidence
- the benefit which arises must outweigh any potential harm
- a proposed benefit must not be too vague, intangible or remote

Burden of proof

- on a registration application, the burden of showing that a particular purpose is for the public benefit is in the first instance a matter for the applicant
- the applicant has the burden of establishing that the claim of benefit is more likely than not to be true
- evidence must be of a type of which judicial note can be taken – i.e. evidence which a court would recognise

5.2 Sources of evidence

In a registration application, the onus is on the applicant to provide us with the necessary evidence that the method offered by the organisation is capable of delivering the claimed benefits.

Detailed evidence databases are maintained by:

- NICE
- the Cochrane database
- NCCIH at PUBMED

The USA's National Centre for Complementary and Integrative Health provides summaries of many therapies including a base line summary.

The website of The Complementary and Natural Healthcare Council, also provides information about the methods it regulates and the medical conditions they are recognised as addressing.

Applicants should make reference to the range of evidence contained in these databases. There are other established databases of evidence which might also be referred to. If the evidence the applicants are seeking to rely upon is not referred to then the applicants would be expected to explain the nature of the evidence they are relying upon compared to these or other recognised databases.

5.3 Weight of evidence when considering scientific and objective evidence of benefit

All claims made for the efficacy of a method to cure or treat specific conditions must be substantiated with evidence, which must be evidence that a court could recognise.

The weight of evidence will also depend upon the nature of the particular research which may include:

- systematic reviews
- randomised control studies
- cohort studies
- observational studies
- meta-analysis

and factors may include:

- the source of the evidence – is it sufficiently independent and authoritative?
- is the evidence accepted in academic or scientific circles and has it been peer reviewed? If not, can any differences of expert opinion be rationally explained?
- does the evidence fully address the claims made for the method?
- what is the method's relationship with conventional medicine?

In considering the different forms of evidence, caseworkers should consider the weight which may be attached to such evidence. Relevant considerations may include:

- how large was the study?
- was the study a controlled clinical trial?
- what steps were taken to minimise bias?
- are there potential conflicts of interest?
- how do reported results compare with previous studies?
- what does it mean when the results of a study are described as statistically significant but not clinically significant?
- how old is the study?
- any other evidence which is inconsistent with or contradictory of the evidence provided

We must be satisfied that, taken overall, the evidence is of the quality that would be accepted by a court as demonstrating benefit.

Caseworkers should take legal advice if, based on the evidence provided, they are uncertain of the weight of evidence provided.

In some cases it may be necessary to seek an independent expert review of the evidence.

Given the range and variety of possible therapies and possible sources of evidence, the examples referred to in this guidance are not intended to be prescriptive, and it is open to the Commission to take account of any other evidence which we consider relevant, provided that it meets the requirements set out in this guidance.

5.4 Evidence appropriate to circumstances

The evidence we require will depend on the claims made for the relevant CAM therapy. In particular, where a therapy claims to cure, diagnose or treat a particular condition or symptoms, as opposed to providing relief, then objective research to evidence this will be required.

Further where a therapy claims to treat a condition, there is an inherent increased risk of harm to recipients that they may delay or postpone conventional medical assessment and treatment of demonstrated clinical effectiveness. In these circumstances, particularly clear and compelling evidence of efficacy to demonstrate benefit which outweighs the potential harm will be required.

The issue is most acute where a therapy is actually offered as a substitute for conventional treatment, particularly where it is claimed that the method is capable of diagnosing or curing the conditions in question.

5.5 Complementary or alternative?

Although we don't need the applicants in all cases to provide us with detailed evidence of efficacy of the therapy (see section 6 for when this is the case), we do always need them to tell us, for the reasons given in section 5.4, whether the method is being used as a complementary or alternative method.

5.6 Evidence based on subjective reporting by patients.

Some benefits provided by some CAM therapies may be more difficult to measure or test through scientific trials than those of conventional medicines. Where the claimed benefit relates to effects that are not adequately demonstrable by medical means (such as physical, physiological or biochemical data) or observable by clinical observation then evidence based on patient reporting will be considered.

Such evidence may measure elements of:

- physical health: fatigue, pain intensity, pain interference, physical function, sleep disturbance
- mental health: anxiety or depression
- social health: ability to participate in social roles and activity

The subjective measure in such cases is that the patient themselves reports feeling better or less suffering.

Where the evidence relies on self-reported evidence this is often referred to as Patient Reported Outcomes through use of PROM (Patient Reported Outcome Measures)

Some clinical observation and research may also to an extent depend upon questioning of the patient (subjective) and making an assessment based upon that, often referred to as observational reported outcomes.

If the benefit is one which ought to be capable of being evidenced by objective means, measurable by scientific trial or observation, then objective evidence of benefit will be required to establish public benefit. However, if the benefit claimed is one which is necessarily subjective based on an individual's reported feeling, and is incapable of proof by objective evidence (such as people with an illness feeling comforted as a result of the use of a therapy) then, if the subjective evidence is sufficiently robust, we can accept this as evidence of benefit.

In assessing whether the research of findings based on subjective evidence is sufficiently robust, relevant considerations will be similar to those outlined in section 5.3 of the guidance. This will include the methods used for collection of data, the reliability and response rate of the sample and whether the PROM has been subject to validation and testing.

It is unlikely that individual patient testimonies or evidence of long established use alone will be sufficient in the absence of more rigorously developed evidence such as a formal PROM or other supporting evidence of benefit. While subjective evidence, including Patient Reported Outcomes, may be

sufficient evidence for relief of suffering it is not, based on recognised scales of evidence, reliable evidence of the clinical efficacy of a treatment.

5.7 Mechanism of benefit

Where the evidence of a physical effect or efficacy of treatment has not been established by objective evidence then we would consider the purported mechanism of physical effect by which it is claimed the benefit arises. In some cases, where neither an objective effect nor a demonstrable mechanism of effect can be evidenced to support the claim made, we may consider this to be an indication of detriment arising from the furthering of the purpose.

In the provision of some CAM therapies the benefit may arise from the circumstances of the treatment which themselves provide support and comfort. The distinguishing feature of the treatment would not be considered in isolation if sufficient evidence of benefit can be established.

6. Methods already recognised as being beneficial

For some methods the benefit claimed may have been examined and accepted by other bodies (or there may be a consensus of scientific opinion which acknowledges benefit). Where this is the case it may not be necessary for the applicants to provide us with detailed scientific evidence to support their application.

For example, an organisation aims to diagnose and relieve pain arising from musculoskeletal problems using chiropractic and osteopathy. Chiropractic and osteopathy are methods recognised on the basis of medical science as being capable of doing that.

Where an applicant has demonstrated that it will adopt a particular recognised CAM method and it has already been recognised as beneficial, we don't need to see the detailed scientific evidence of the efficacy of the method in order to decide if the purpose is for the public benefit. This is because recognition of the method will have been gained following robust and independent scrutiny of the available evidence. In these cases we can accept that the efficacy of the method has been demonstrated. For example, where the therapy has been appropriately recognised by NICE we would not seek further evidence.

Caseworkers should seek further advice from a legal officer on whether there is sufficient evidence of recognition of benefit and whether further evidence is required.

Acceptance of benefit may change

Changes in medical science and common understanding are such that what may be accepted as for the public benefit is likely to change over time. Previous decisions may therefore fall to be reviewed from time to time.

7. The risk of harm and how this impacts on public benefit

When considering whether the purpose of a CAM organisation is for the public benefit our approach is to consider both the benefit and harm.

The Commission recognises that:

- therapies which have not been rigorously tested before being made available for use carry an increased risk of harm to those receiving them; and
- people who are ill may be willing to try (and pay for) therapies in the hope of a cure and may experience harm as a result

Public benefit will be affected if the potential for people to experience harm from a CAM therapy outweighs the benefits that can be gained. To satisfy the public benefit requirement, therefore CAM organisations must be able to show that any risk of harm has been minimised or reduced so that the harm does not outweigh the benefits.

The main risks associated with CAM are:

- poorly administered, a CAM method could cause physical or psychological harm
- CAM has the potential to exploit people who, because of their condition, are especially vulnerable
- using CAM as an alternative to conventional medicine may mean that people who need a medical diagnosis and treatment do not get it

See section 7.2 for further information on the evidence that trustees must provide to deal with these harm factors.

7.1 Assessing the risk of harm

When considering harm factors in relation to CAM, what we are looking for is evidence that any potential for harm is minimised or reduced so that the harm does not outweigh the benefit. The greater the risk, the more compelling the evidence will need to be to establish that those risks will not outweigh the benefits.

The risk of harm is likely to be greater where:

- methods claim to cure or diagnose conditions
- the therapy is offered, or recommended, as an alternative to conventional medicine
- the way the therapy is administered means those receiving it could be vulnerable to harm or abuse
- there is little or no formal regulation and/or supervision of practitioners carrying out the method to ensure it is delivered safely

The risk is likely to be reduced where:

- the method offers relief from a condition but does not claim to cure or diagnose it
- the therapy is offered alongside but not instead of conventional medicine (and people receiving the treatment are told that they are receiving it on that basis)
- the therapy is non-invasive
- the therapy does not require recipients to remove clothing or make themselves vulnerable in other ways

- practitioners are required to register with a single regulatory body, undergo formal training and are required to meet standards of competency to receive a professional qualification, ongoing professional training and adhere to defined professional standards when administering the treatment
- regulation includes formal complaints and grievance procedures for when standards are not met
- practitioners are required to have insurance to protect those receiving the therapy

Section 7.2 sets out the information we require from trustees to show how the risk of harm is managed.

Caseworkers should take advice from a mentor or legal officer if they are unsure whether the evidence provided demonstrates that the risk of harm does not outweigh the benefit.

7.2 Information the applicants need to provide to show the risk of harm resulting from use of the CAM does not outweigh the benefit

The information we need the applicants to provide in relation to managing the risk of harm will depend on the CAM method in question, and the potential for harm associated with it. In general, applicants should be able to confirm most, if not all, of the following points to us as evidence that the CAM they are using is safe:

- the practitioners they use to administer therapies are (where one exists) members of the professional standard-setting regulatory body applicable to the CAM method being used, and are bound by its codes of ethics, conduct and practice. We would expect the code to have been registered with the Professional Standards Authority or similar body
- practitioners used to administer therapies must demonstrate a required standard of competency to deliver the method safely
- if a method is intended to be used as a complement to conventional medicine, then recipients are told this and advised to contact their GP or other practitioner of conventional medicine
- where a recipient's condition is outside the practitioner's area of expertise (and therefore beyond the scope of what the therapy is capable of achieving), the practitioner advises them to contact their GP
- practitioners do not act contrary to the advice of the recipient's practitioner of conventional medicine
- there are complaints and/or disciplinary procedures in place for when a therapy or course of therapy fails to benefit the patient in the way they have been told it will, or if it harms them
- where the nature of the therapy warrants this, practitioners have insurance to protect those receiving the therapy

In some cases it may also be necessary to ask whether CAM organisations have in place other forms of mitigation against relevant risks.
See also section 8 on Regulation.

When assessing this information we must be satisfied that, taken overall, the evidence is of the quality that would be accepted by a court or Tribunal as demonstrating benefit.

Evidence of the absence of harm does not however establish the benefit of a therapy.

8. Regulation of CAM

Regulation of a CAM, whether by statute or voluntary self-regulation, can be a significant factor in deciding whether the benefits are outweighed by the risks of harm. Where a CAM method is used it is important that there are controls and safeguards to ensure the therapy is administered safely. The presence of a formal regulatory framework (usually through a single regulator) will be helpful in showing how this is achieved and what the proven benefits of the therapy are in relation to the risk of harm.

Where there is no such framework, we take into account the nature and level of the risk of harm to recipients of the therapy in the particular circumstances of the applicant organisation. The greater the risk, the more necessary it will be for the CAM organisation to show how the method is approved and regulated and how its practitioners are trained and regulated, in order to confirm that the risks are outweighed by the benefits.

Where the regulation of practitioners is in accordance with the standards and framework approved by a recognised body such as Professional Standards Authority, Health and Care Professions Council or Complementary and Natural Healthcare Council, we don't need to examine the requirements in detail. In these cases, applicants should confirm that the organisation and its practitioners will operate fully within the relevant regulatory requirements.