

Outcome report

The use and promotion of complementary and alternative medicine: making decisions about charitable status

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The Charity Commission's role

The Charity Commission is the regulator and registrar of charities in England and Wales. We are an independent, non-ministerial government department accountable to Parliament against statutory objectives set out in the Charities Act 2011.

Our purpose, set out in our <u>Statement of Strategic Intent</u>, is to ensure charity can thrive and inspire trust so that people can improve lives and strengthen society. All charities are custodians of what it means to be a charity in the eyes of the public, as is the Commission.

As registrar we are responsible for maintaining an accurate and up-to-date register of charities. This includes determining whether organisations are charitable and should be registered, and removing those which are no longer considered to be charitable, have ceased to exist or do not operate.

About the review

The Charity Commission has carried out a review of our approach to deciding whether organisations that use or promote complementary and alternative medicine (CAM) therapies are charities. The Commission has a responsibility to review areas of its policy and guidance from time to time, to ensure that its approach to assessing applications reflects the available evidence and the current state of the law.

This work has not been about determining whether any one CAM therapy or approach is 'good' or 'bad', but confirming whether organisations which use or promote these therapies meet the legal test to be charities. Nevertheless, registration of an organisation as a charity is recognition that it is set up to benefit the public.

The review involved us examining the current state of the relevant law and our operational guidance for case workers in our registration function. We sought external input and advice and ran a public consultation, which received around 670 individual responses. A <u>summary of responses</u> received is available on GOV.UK, and a short overview as to how these responses have informed the outcome of the review is set out in a separate document accompanying this report.

The <u>consultation document</u> explains the meaning of some of the terms we have used in this report.

CAM organisations and charitable status

The Commission has recognised the potential for CAM organisations to be registered as charities since at least 1975, and included in its Annual Report for that year an explanation of its approach to what it then termed "fringe medicine".

CAM organisations are diverse in the treatments and therapies they use, their size and income and the nature of their work. Some provide advice to the public on certain treatments, others provide treatments or therapies directly, and others serve as umbrella organisations or as training providers for the use of certain treatments. Some may promote

certain treatments as alternatives to conventional medicine, while others promote the use of therapies to complement rather than replace conventional medical care.

CAM charities are most likely to have aims around the advancement of health or the saving of lives or the relief of need arising from age, ill-health, disability or other disadvantage, although others may fall into different categories, such as charities for the advancement of education. The advancement of health includes the relief of sickness, disease and human suffering.

Whether an organisation is a charity is a question of law, and the Commission can only make decisions about charitable status in line with the legal framework. Put simply: to evidence charitable status, an applicant organisation must show that its purposes are exclusively charitable and for the public benefit. This means that applicants must provide evidence that their intended purposes can benefit the public, and will not result in any inappropriate harm. This basic principle applies to all applications for registration, including CAM organisations. More information about the legal framework is set out in a separate document accompanying this report.

In registering a CAM organisation as a charity we are not endorsing any treatment or confirming its medical efficacy, but confirming that the organisation itself meets the test for charitable status, including that of providing public benefit.

The Commission's approach to registering CAM organisations as charities has, to date been, set out in operational guidance, which is used by our case workers. The legal basis for that guidance has been explained in the <u>Annex to our published decision</u> on the charity the Soteria Network.

Outcome of the review

Our review has confirmed that the basic legal principles that apply to our work in assessing applications for charitable status by CAM organisations remain unchanged. But as a result of our review, we are updating our approach to assessing CAM organisations against those legal principles. The changes we are making will mean that we may ask for different information from some new applicants for registration, and we will need to consider whether any currently registered CAM charities may be affected as a result.

We believe that the result of the review will allow us to increase the confidence that the public can have regarding which CAM organisations are on the register of charities, while limiting any potential for harm.

How and why our approach is changing

To date, the questions we have asked when assessing whether a CAM organisation can provide public benefit have been focussed on whether there is evidence of the medical efficacy of the treatment, or treatments, in question.

Our review has shown that this approach can usefully be updated, in two main ways.

First, we have amended our guidance to take account of the range of evidence sources available to demonstrate public benefit and of developments in knowledge over time.

Second, our review has established that evidence of medical efficacy (such as findings generated from scientific trials) that a certain treatment has measurable beneficial medical impact is not the only way in which a CAM organisation might demonstrate that it provides public benefit.

Our review has established that some CAM organisations do not aim to provide the same benefits to the public as more conventional medical organisations might. Instead their purposes may relate to relieving suffering or providing comfort to patients, either generally or in the context of certain medical conditions. In such situations, evidence of benefit may come in the form of outcome reports by patients, or observational studies based on patient responses. This type of evidence may, for example, be the best available source to evidence a patient's level of pain, functional limitations, or other symptoms (fatigue, mood, and so on). In all cases, the evidence provided must be of a type which a court would recognise.

Example: An organisation claims to offer relief and comfort to people undergoing conventional medical treatment for cancer through the provision of complementary therapies. When it applies to register, it must demonstrate public benefit like any other applicant. But it would not necessarily need to show that the therapy has any positive effect on the medical outcomes for cancer patients. Instead, it would need to provide reasonable evidence that its approach is capable of providing relief and comfort to those undergoing cancer treatment, for example in the form of robust patient reported outcome studies.

The key question we will be asking when assessing CAM applications in future is what appropriate evidence the applicant can provide for the claims it makes. In other words, the evidence an applicant provides will need to match the claims it is making.

As well as widening the focus of our approach to include evidence to support claims regarding the relief of suffering, we are clarifying and focussing the requirements for appropriate scientific evidence if a CAM applicant makes claims that its therapy can produce particular physical outcomes.

Our updated operational guidance for case workers explains this in more detail, and explains what types of evidence we will require to support claims of medical efficacy. It also explains where we accept therapies as having already been recognised by other bodies which have considered the available evidence.

As our updated guidance makes clear, the categories of evidence we will consider are not exhaustive, and we will consider any evidence which is appropriate and relevant to the claims which an applicant makes.

What these changes mean for the public

We consider that the changes outlined above serve to ensure that our decisions on registering CAM organisations continue to be robust and will reduce any potential for harm, while promoting informed public choice regarding charities and donations, and ensuring that

organisations that are capable of providing public benefit can demonstrate this without being hampered or restricted by requirements for inappropriate types of evidence.

In future, the public can have greater confidence that a CAM charity, once registered, has been able to demonstrate that it has evidence to support the claims it makes about its treatment.

What these changes mean for CAM organisations applying to register

CAM organisations seeking registered charity status will need to be very clear about the benefit they consider their treatment can provide, and they will need to ensure that they have evidence to prove that benefit. Those claiming (for example) to cure diseases will need to provide robust medical evidence.

The ongoing regulatory oversight of CAM charities

This review focused on the evidence we require to determine whether an organisation set up to promote CAM is a charity in law and should therefore be registered with us. But the Commission's oversight and scrutiny of charities does not end with registration. The trustees of all charities must comply with legal duties and responsibilities around the management and governance of their charity, and the Commission works to ensure trustees comply with those requirements.

Our <u>safeguarding strategy</u> makes clear that a charity should be a safe and trusted environment. With regard to CAM organisations registered as charities, we will take very seriously any concerns about the safeguarding and treatment of people, including in the way that a treatment and its benefits are described to potential beneficiaries. So while registration as a charity is a meaningful and important recognition of the potential public benefit provided by an organisation, it in no way precludes our taking regulatory action where we have concerns about a charity's activities and operations or about trustees' oversight of their charity's work.

How consultation responses informed the outcome of our review

The general area of CAM therapies, the benefits they provide and the risks associated with their use is both complex and strongly contested by different groups.

As with some other areas of charitable status, views regarding CAM therapies are very deeply held in some cases, including by those who strongly believe that CAM therapies are beneficial and those who believe either that they are not beneficial, or that they are actively harmful.

This complexity and diversity of opinion were reflected in the consultation responses we received. Responders' views differed on all of the questions in our consultation document. Not all of the information we received was directly relevant to our review. Some responses were more relevant to those involved in developing clinical guidelines and/or commissioning health services, or in questions as to whether or not CAM therapies should be available/publicly funded/subsidised, or how their provision should be regulated.

As explained above, the purpose of our review was not to form a general view on whether CAM therapies are 'good' or 'bad', or indeed how and whether they should be made available through public health provision; instead, we sought views on the level and type of evidence we should require from CAM applicants to determine whether or not they are, in law, charities.

As well as the debate over what evidence should be relied upon to determine whether or not a CAM therapy provides a benefit, views differ over whether all types of CAM therapies are beneficial to the public, what any benefits arising from CAM therapies are, and the reliability of various forms of evidence.

To give one example, while some responders identified the use of randomised controlled trials (RCTs) as the "gold standard" for the assessment of the effectiveness of medical treatments, others argued that RCTs, and other forms of clinical trial, are not applicable to CAM therapies.

Responses referred us to a great deal of detailed argument regarding scientific evidence, legal issues and the social context of CAM therapies and to a large amount of supporting literature and sources of evidence. To the extent that these were relevant to the decision on our revised approach, these have been considered in the framing of the updated guidance.

What we will do next

Our revised approach, as described in this report and in the attached documents, is based on our considered understanding of the legal framework for charitable status as applicable to CAM organisations, and represents our approach to implementing that framework in assessing charitable status in such cases.

We will consider whether any past registrations of CAM organisations should be revisited, and whether a different decision might have been made had our updated approach been in place.

Our preliminary view is that, for the vast majority of registered CAM charities, no action will be needed, either because the efficacy of the relevant treatment has already been established under our previous approach, or because it is clear that benefit can be demonstrated under the current approach.

In some cases, it may be that we recommend that a registered CAM charity amend its objects, so that they are limited to what can clearly be demonstrated by the available evidence.

If it appears to us that a past registration under our previous approach may have been mistaken, in that the relevant organisation cannot properly be considered a charity, then it will be necessary to remove it from the register, in line with our statutory functions and duties. However, no such decision has been taken in any case as a result of this review, and this may not apply to any currently registered charities.

This work is under way, and we will be publishing further updates at a later stage.