CHARITY COMMISSION
FOR ENGLAND AND WALES

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

The consultation

A summary of the key themes arising from the consultation was set out in the report on the consultation published in December 2017.

Below we set out how these issues have been addressed in our change of approach, following this review and our consideration of the points made in response to the consultation.

Question 1: What level and nature of evidence should the Commission require to establish the beneficial impact of CAM therapies?

We have taken into account the wide and diverse categories of evidence described by consultation responders, alongside our own investigation of the area, and have assessed the applicability of the available forms of evidence under the charity law framework.

Responders' views differed not only as to what evidence we should take into account, but on the relative strengths and weaknesses of different forms of evidence.

The legal framework requires the Commission to identify the particular purpose of the relevant institution, then identify whether that purpose is within the descriptions of purpose in charity law, and whether it is for the public benefit.

Further detail of the evidential requirements is explained in the legal framework document accompanying this report.

Some responders urged us to ensure that the evidence we consider is appropriate to the particular benefit being claimed. Our revised approach emphasises this approach and focusses on the claimed benefit arising from a particular purpose, rather than specifically on medical efficacy (which is one way in which benefit can be shown*).*

There are a number of established, authoritative sources of evidence which act as a helpful starting point, as referred to in our revised guidance. We recognise that the sources of evidence specifically referred to in our guidance are not exhaustive. We will not treat any specific form of evidence as either necessary or sufficient in itself to establish benefit, and we will not *necessarily* disregard any broad particular category of evidence. This allows us to recognise the diversity of CAM therapies available and of the range of potential charitable purposes which might be furthered by their use, while ensuring that we only refer to evidence which is appropriate for the particular purpose in any given case.

A significant number of responses expressed support for the Commission's approach as set out in its previous guidance, although this was not universal. Our revised guidance updates and builds on the previous guidance, and is based on the same fundamental legal framework.

We have recognised that some types of benefit (particularly in the area of relief, support and comfort to patients), may be evidenced by reference to what might be termed subjective evidence, based on patient reported outcomes. Where such evidence is sufficiently robust, based on validated reporting and research methods then we accept this may be sufficient to establish the benefit in appropriate cases. Isolated patient testimony in itself is not likely to be sufficient.

We continue to recognise the statement of the House of Lords Science and Technology Select Committee in 2000 that the Committee was:

'*satisfied that many therapies listed in our Group 2 [a categorisation of therapy within the report] give help and comfort to many patients when used in a complementary sense to support conventional medical care even though most of them also lack a firm scientific basis. Nevertheless in relieving stress, in alleviating side effects (for example of various forms of anti-cancer therapy) and in giving succour to the elderly and in palliative care they often fulfil an important role*.'[1]

We also recognise the distinction between the evidence which may be required to establish benefit in charity law terms and that which is used to make decisions relating to clinical guidance and policy.

Many responders urged us to ensure that the same test is applied to CAM organisations as to organisations which use or promote conventional therapies. In our revised approach, as in our previous approach, CAM organisations are treated consistently with other organisations regarding the test for charitable status (i.e. that they must be established for exclusively charitable purposes). So far as the purposes which CAM organisations further are the same as those which are furthered by charities operating in conventional medical fields, the tests set out in the revised guidance would also apply, although they may not be technically within the scope of this particular guidance document.

We were referred to the processes used by other agencies and authorities in assessing CAM therapies. We cannot adopt the criteria or processes that other organisations use wholesale, as the Commission's assessment is of charitable status under the law of England and Wales rather than of any other test. However, this information, and in some cases our direct engagement with other organisations, has helped us to understand the relevant issues and to develop our approach. Our revised guidance makes reference to the circumstances in which we will rely on evidence produced or assessments made by other bodies.

We have considered carefully whether we should require evidence of benefit to demonstrate a mechanism of effect which is plausible, or which can be separated from a "placebo" effect.

[1] House of Lords Science and Technology Committee Sixth Report, 2000.

In our view the purported mechanism of effect of a treatment is a relevant factor to take into account in assessing public benefit. The promotion of a belief in a medical effect which cannot be supported by objective evidence may constitute a detriment, which the Commission would need to take into account in assessing public benefit; but this does not mean that a treatment must always be able to demonstrate its mechanism of effect to a particular standard in order to show public benefit.

We will assess the purposes of an institution as a whole in determining charitable status. In the provision of some CAM therapies, benefit may arise from the circumstances of the treatment which themselves provide support and comfort. The distinguishing feature of the treatment – the particular form that the treatment takes - would not be considered in isolation if benefit can be established from the purpose as a whole.

The absence of evidence of harm is not itself evidence of benefit. However in order to show public benefit, a therapy must be shown to be capable of being delivered safely and effectively, with any potential harm mitigated so that any resulting harm or risk of harm does not outweigh the benefit provided.

We are aware that the state of scientific evidence bases changes over time. This is reflected in the charity law framework which recognises that what may be regarded as beneficial to the public in one era may not be in another.

Question 2: Can the benefit of the use or promotion of CAM therapies be established by general acceptance or recognition, without the need for further evidence of beneficial impact? If so, what level of recognition, and by whom, should the Commission consider as evidence?

Some people who responded to the consultation argued that widespread acceptance or use of a therapy should be evidence of benefit. Others argued that it should not, as even very widely held beliefs might be based on misjudgements.

For some charitable purposes, public benefit may be recognised where there is a common acceptance or understanding – but that depends on what benefit is being claimed, and whose acceptance or recognition is relevant.

Some responders referred us to the acceptance of particular therapies by particular groups or communities, such as medical professionals, or particular authorities.

In some cases elements of medical benefit arising from CAM therapies may have been accepted by other bodies on the basis of independent scrutiny, such as NICE or ASA. Where this is the case the benefit may be accepted without need for further evidence.

Similarly we would take note of the findings of Parliamentary inquiries such as the House of Lords Science and Technology Select Committee, to the extent that this is relevant in particular cases.

If conventional medical professionals would refer patients to practitioners for a particular therapy then this can be taken as evidence of benefit and would be considered in the same way as other evidence presented.

Evidence of widespread use or use over a long period of time, while not irrelevant to an assessment, appears to be evidence of a circumstantial nature and we would not accept this on its own in most cases. Evidence that a large number of people believe that a therapy is effective is not necessarily evidence that the therapy is effective.

Changes in medical knowledge mean that common acceptance or understanding will change over time.

Question 3: How should the Commission consider conflicting or inconsistent evidence of beneficial impact regarding CAM therapies?

Responders suggested a range of approaches to this issue. Some took the view that, if the evidence for the benefit provided by a therapy was inconsistent, then it should not be accepted as providing public benefit. Others thought that the evidence should be considered as a whole. Some referred us to recognised hierarchies of evidence, under which some forms of evidence are considered more reliable than others.

We recognise that different sources of evidence may produce different answers to the same, or similar questions, and that there are differences in the standard and reliability of evidence.

There are a number of recognised and authoritative databases which may be used to assist in identifying the range of evidence together with evidence summaries. We have identified a number of key questions in our guidance to help caseworkers in assessing evidence.

We recognise in some cases that it may be appropriate to seek independent expert opinion.

As with any application for registration, we will assess whether public benefit is demonstrated by CAM organisations based on the balance of probabilities. This means that applicants do not need to show with absolute certainty that a claimed benefit arises, but that it is more likely than not to do so.

Question 4: How, if at all, should the Commission's approach be different in respect of CAM organisations which only use or promote therapies which are complementary, rather than alternative, to conventional treatments?

Some responders to our consultation questioned the use of the term "complementary and alternative medicine", including whether the concepts of complementary and alternative could be separated.

We continue to recognise these terms as appropriate in this area, and also to recognise the distinction between the two, where possible. We consider that alternative therapies may give rise to a greater risk of harm than complementary treatments, on the basis that alternative therapies may divert people from conventional treatments which have been shown to be effective.

We do not take a different approach to assessing whether a benefit arises, depending on whether a treatment is complementary or alternative – the test must still be satisfied on the balance of probabilities. However, the risk of harm presented by a therapy which is provided

as alternative may mean that the demonstrable benefits must be greater in order to satisfy the test for charitable status.

Question 5: Is it appropriate to require a lesser degree of evidence of beneficial impact for CAM therapies which are claimed to relieve symptoms rather than to cure or diagnose conditions?

Some responders thought that a lesser degree of evidence would be appropriate, while others suggested that there should be no difference. Some took the view that the risk of harm in palliative care cases is lower, and there is an argument that the degree of evidence needed in such cases should be lower on that basis. Some responders did not think that the distinction could be maintained.

The evidence required will depend upon the claim. As explained above in relation to question 1, it may be possible to show that a purpose produces benefits in the form of relief or comfort based on reporting by patients. Where the claim is made to treat or cure an underlying medical condition, capable of scientific objective measurement, appropriate medical evidence should be provided.

The evidence required will therefore depend upon the stated purpose and the claims made for the therapy.

The same level of evidence is required in each case, which is a level of evidence necessary to establish the benefit on the balance of probabilities.

Whether or not a purpose is charitable will not in our view depend upon the seriousness, or the potential consequences, of any condition which is proposed to be treated, but on whether or not the purpose will produce the benefits which are claimed for it.

Question 6: Do you have any other comments about the Commission's approach to registering CAM organisations as charities?

A wide range of issues were raised in the responses reflecting the diverse range of opinions held. These included a range of public policy matters, such as whether CAM therapies should be available/publicly funded/subsidised, the cost and practicalities of undertaking research, and how the provision of CAM therapies should be regulated. Issues were also raised in respect of the interests of particular groups and the treatment of CAM as against providers of conventional medicine.

The issues raised were helpful in understanding the context of the provision of CAM.

As noted above, the issue for the Commission to determine in the context of this review is how to assess whether or not CAM organisations are charities, in accordance with the legal test and in line with our statutory functions and duties. That requires public benefit to be demonstrated. Wider issues of public policy, medical regulation and the funding and conduct of scientific research are beyond the scope of this review, and the Commission's statutory role. The legal test for charitable status is the same for CAM organisations as it is for any other type of organisation.

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 that the organisation meets the test for charitable status including that of benefit to the public.