Submission to the Charity Commission for England and Wales consultation on
The use and promotion of complementary and alternative medicine: making decisions about charitable status

Memo from Sense about Science and the Royal Pharmaceutical Society

A Level and nature of evidence
The Commission’s current approach acknowledges that some CAM therapies have been recognised in legislation or amongst the wider public. As part of this review the Commission is considering whether any particular degree of public or regulatory recognition can be used as evidence to support the use or promotion of CAM therapies being charitable.

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

- To establish beneficial impact, the evidence should be appraised by an expert review group based on a standard approach used by other bodies such as NICE, SIGN and MHRA, described in more detail below.
- Charities should provide studies to back up their claims for the expert review group to appraise. The types of study would be ideally, systematic reviews or well conducted, registered and reported randomised controlled trials. Where this high level of evidence does not exist other types of studies, published as original research papers in peer-reviewed, recognised journals may be included. However any ultimate recommendation should make clear the level of evidence on which it is based using a recognised hierarchical classification.
- The level of evidence required should be proportionate to the perceived risk.
- As well as aspiring to make decisions based on the highest level of evidence the quality of the study must also be assessed. Evidence derived from a poorly conducted randomised controlled trial may be less informative and valid than a well conducted cohort study.
- For the evidence appraisal process, methodologies for evidence synthesis have already been developed to assess the quality or certainty of that evidence, for example GRADE.\(^1\) We recommend an expert review group adopts processes already developed by regulatory bodies or royal colleges, to assess whether studies have been well conducted and allow findings on whether treatments or interventions do more good than harm to be reported with confidence.
- Expert review group appraisal is essential for a flexible and intelligent approach and to avoid a scenario where, for instance, a charity providing massage for palliative care that makes no claims of medical benefit is denied charitable status alongside a charity fundraising for and promoting treatments that are likely to do more harm than good. We recognise, of course, that this is not the Charity Commission’s intention.

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- To support the Charity Commission’s establishment of an **expert review group** to provide evidence appraisal when organisations apply for charitable status, Sense about Science and the Royal Pharmaceutical Society would be very willing to connect the Charity Commission to regulators, professional bodies and experts in evidence, including pharmacists, to either provide expertise and/or appraisal directly or to share their knowledge, processes and evidence appraisal methods appropriate for different contexts.

- The expert review group could include clinical researchers, researchers with expertise in evidence synthesis, and statisticians.

- It is worth noting that the evidence base changes over time, which could alter the answer to the question of whether a treatment provides beneficial impact. This could require the commission to review its decisions should new evidence come to light.

**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?

- No. No degree of general acceptance or recognition – whether public or regulatory – can establish the benefit of the use or promotion of CAM therapies in the absence of robust evidence (see response to question 1).

- This is one reason why the availability of homeopathy on the NHS and from some pharmacies is problematic. The [2010 House of Commons Science and Technology Committee report on homeopathy](https://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/4502.htm) concluded that homeopathic remedies perform no better than placebos, and that the principles on which homeopathy is based are "scientifically implausible". This is also the view of the Chief Medical Officer, Professor Dame Sally Davies. Yet there is a population of users who remain convinced it has been of benefit and it remains available from some practices through the NHS. This availability on the NHS and from some pharmacies lends it a credibility which is removed from – and in this case contradictory to – its efficacy. Further, although by its very nature homeopathy is unlikely to be directly harmful it may be indirectly harmful by delaying or even substituting for access to conventional treatment.

**B Conflicting and inconsistent evidence**

*In some cases there may be conflicting evidence as to whether or not a particular treatment is effective; or there may be only a very limited amount of evidence which supports claims of beneficial impact for a treatment.*

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

- Conflicting or inconsistent evidence should be assessed in the context of the whole body of available evidence – how does any evidence suggesting a therapy has beneficial impact weigh up against any evidence showing no benefit or in fact harm? This assessment can only be made by expert review group appraisal of the body of evidence, and we recommend applying processes already developed by regulatory bodies and royal colleges and other professional bodies to assess the strength and certainty of the evidence (see our response to question 1). The level of evidence required should be proportionate to the perceived risk.

- We believe a set of questions or criteria cannot be applied in isolation, without unintended consequences, such as denying charitable status to organisations who are providing public benefit or missing charities who offer treatments which could be causing more harm than good. Only with a bespoke approach such as an evidence appraisal by an expert review group can recommendations be applied in areas of uncertainty where judgement is needed to avoid the problems of over and under inclusion which can come with regulation.

**C Alternative therapies and the risk of harm**  
When considering the benefits which are claimed for a CAM therapy, the Commission considers whether there is any potential for harm as a result of the use or promotion of that therapy. Where an alternative therapy is offered instead of conventional therapies for curing a medical condition, there is a risk of harm if people who are in need of treatment may not seek, or may delay seeking conventional treatment as a result.

**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?**

There is potentially a significant problem associated with the use of complementary treatments which are used internally, such as herbal medicines, which in contrast to conventional medicines often contain a complex mix of active ingredients. In general there is less rigorous evidence of either their effectiveness or safety, including adverse reactions and interactions with conventional medication, either prescribed or purchased ‘over the counter’. Whilst in the UK any suspected adverse effect or drug interaction should be reported through the Yellow Card system, in practice the number of reports is low. Although herbal products may be perceived as ‘natural’ and less likely to cause problems than conventional medicines this is not necessarily the case. Anything that has a beneficial effect is also likely to have other unwanted effects.

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It is well established that there are some herbal therapies that do interact with other treatments a patient is receiving. For example St. John’s Wort is a potent inducer of both cytochrome P-450 enzymes and there are reported clinically significant interactions with, for example, the immunosuppressant drug cyclosporine, the antiretroviral agent indinavir, oral contraceptives, digoxin, and benzodiazepines, among others. Golden seal is another herbal medicine with reported interactions. There is often a low level of evidence about herbal treatments and just because there have been no validated reports of interactions it does not mean they won't occur. For instance, if a patient is taking a conventional medication that has a narrow therapeutic window, taking any herbal treatments which might have even a low level interaction, could cause harm from either enhancing the conventional medicine’s effect or rendering it ineffective. A narrow therapeutic window means that a drug is only effective at a very narrow range of doses and so anything that changes its metabolism, and for example changes the active levels in the body, will interfere with the conventional treatment. For the same reasons herbal treatments should also be avoided in pregnancy and lactation, as the effects are unknown.

The Royal Pharmaceutical Society has found that patients often do not tell their doctors when they are taking complementary treatments. This is problematic and can result in poorer health outcomes for the patient for reasons such as those outlined above.

The WHO promotes the safe and effective use of traditional medicine (eg traditional Chinese or Ayurvedic medicine) by regulating, researching and integrating traditional medicine products, practitioners and practice into health systems, where appropriate. Appropriate use will most likely be achieved with the involvement of qualified professionals and high quality products. We would therefore expect that any charity involved in providing alternative treatment would ensure input at strategic and individual patient level of appropriate conventionally qualified health care practitioners. We believe our recommendation that evidence of the potential benefits and harms of treatments be appraised by an expert review group is compatible with this WHO guidance.

People facing long-term or chronic conditions – cancer, degenerative conditions such as multiple sclerosis or motor neurone disease, autism, epilepsy, Alzheimer’s– can be searching desperately for anything that might help, and are especially vulnerable to exploitation. We have received reports from patients, carers, practitioners and via medical charities of cases where patients with experience of complementary or alternative treatments have:
- found their condition was aggravated,
- felt pressure to stop taking conventional medication,
- been exposed to risk of infections such as HIV via treatment with unscreened stem cells,
- risked their life savings/homes/jobs on unproven treatments,

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faced pressure from well-meaning friends and family to try things despite a lack of evidence to support them, and have been met with disappointment when they realise they have been sold false hope.6,7

D Palliative alternative therapy
If an alternative therapy is only offered on a palliative basis, to relieve symptoms of a condition rather than to cure or diagnose, the risk indicated at section C may not be the same.

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?

- No. The same threshold or “level and degree of evidence” (see question 1) should be required to support the claim, regardless of whether the claim is “X cures Y” or “only” “X relieves the symptoms of Y”.
- It is worth noting, from conversations with patients and families, it is still possible to do harm at the end of life.

E Other comments relating to the Commission’s approach to making decisions relating to organisations which use or promote CAM therapies
The Commission would welcome any other observations which you may have on its current approach to registering CAM organisations as charities. Please note that the Commission is not consulting on its approach to registering charities generally, but on its approach which applies specifically to CAM organisations.

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

- Charitable status is similar to regulatory approval or the availability of a treatment on the NHS in lending credibility to treatments. We are pleased that the Charity Commission is taking the issue seriously as indicated by this consultation.
- It is worth reiterating the point made by the commission under heading C, that “there is a risk of harm if people who are in need of treatment may not seek, or may delay seeking conventional treatment” due to the promotion of complementary or alternative medicine. It is important that the status of the evidence about benefits or harms that could be caused by treatments is made clear, since patients may not seek conventional treatment for

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reasons which may include, but are not limited to, the belief that the CAM therapy will work and is safe and therefore they do not need to seek conventional treatment.

- We have communicated other potential harms throughout this memo, particularly in our answer to question 4.
- It is also worth noting there are risky treatments either offered or promoted and fundraised for (eg unlicensed stem cell clinics offering unproven treatments), which do not describe themselves as CAM. They promote themselves as new, cutting edge treatments, but the treatments may be being used in a context where there is no evidence of effectiveness or safety, and clear risk of harm. Where such treatments are linked to charities, the Charity Commission should treat those charities’ applications as we recommend for CAM. By applying an expert review group these types of organisations could be captured too.

Signed

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19th May 2017
Background
Sense about Science (www.senseaboutscience.org) is an independent charity that challenges the misrepresentation of science and scientific evidence in public life. We advocate for openness and honesty about research findings, and work to ensure the public interest in sound science and evidence is represented and recognised in public discussion and policymaking. Sense about Science is committed to openness and independence. Sense about Science is a small team working with thousands of supporters, from world-leading researchers to community groups.

Sense about Science worked with patients and medical charities to produce I’ve Got Nothing to Lose by Trying It, a guide to weighing up claims about cures and treatments for medical conditions. First published in 2008 and re-published in 2013, it has been translated into three languages (Italian, Latin American Spanish and Croatian).

The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists in Great Britain. We represent all sectors of pharmacy in Great Britain and we lead and support the development of the pharmacy profession including the advancement of science, practice, education and knowledge in pharmacy. In addition, we promote the profession’s policies and views to a range of external stakeholders in a number of different forums.

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