UK CHARITY COMMISSION CONSULTATION

19th May 2017

RESPONSE BY:
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Please find below the Alliance for Natural Health International's response to the consultation published by the Charity Commission on 13 March 2017: https://www.gov.uk/government/news/charity-regulator-consults-on-its-approach-to-organisations-promoting-complementary-and-alternative-medicines

About the Alliance for Natural Health (ANH) International

ANH is a non-profit organisation working with scientists, lawyers, medical doctors, health practitioners, politicians, consumers and companies to help shape scientific and legal frameworks that widen support for, and adoption of, natural healthcare. We operate principally within the UK, Europe and USA.

Find out more at: www.anhinternational.org

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

It is our view that the Charity Commission is not sufficiently expert in matters of complex scientific and medical assessment to make detailed judgments on the benefit of particular health treatments based on analysis and interpretation of the peer-reviewed literature. Evidence requires review by both scientists and clinicians with backgrounds and extensive clinical experience in the relevant area. Since the Charity Commission has made clear in its guidance for the consultation that it is *not* consulting on "what evidence may exist in support of or against the efficacy of any particular CAM therapy", we have not seen fit to provide evidence.

However, we uphold that the following should be considered by the Commission in relation to the level and nature of evidence:

- **Sources of data.** Plausible or credible scientific evidence from the peer review literature that beneficial impacts have been demonstrated for the relevant CAM therapies. Since CAM therapies are generally multi-modality, are likely to have a strong psycho-social basis born out of the therapist-patient relationship as well as a

biomedical one, evidence should not be limited to measurements of outcomes based on comparing treatments with controls in randomised controlled trials (RCTs), nor should the scientific evidence need to be “generally accepted” or “substantial” as this level of conclusivity would rule out evidence for most public health policies e.g. eating 5 or more portions of fruit and vegetables, reducing daily salt intake below 6 grams, or exercising at least 30 minutes a day.

In terms of the types of evidence, case control studies and observational evidence cited in the peer review literature should suffice on this basis. Where the data allows, a balance of evidence approach based on relevant data can be used. Systematic reviews or meta-analyses, which may or may not include RCTs, may be used. Given the skeptic-led attacks on homeopathy, the key initial driver for the consultation, and that homeopathy is generally regarded as the most controversial therapy, it is ironic that 6 systematic reviews or meta-analyses have been conducted, with 5 out 6 of these showing beneficial effects over and above placebo (see Box 1 below).

BOX 1 – Systematic reviews and meta-analyses of homeopathy

Homeopathy systematic reviews or meta-analyses demonstrating a beneficial effect compared with placebo:

(1) Mathie RT, et al. Randomised placebo-controlled trials of individualised homeopathic treatment: systematic review and meta-analysis. *Syst Rev*, 2014; 3: 142.

(2) Cucherat M, et al. Evidence of clinical efficacy of homeopathy – A meta-analysis of clinical trials. *Eur J Clin Pharmacol*, 2000; 56: 27–33.

(3) Linde K, et al. Impact of study quality on outcome in placebo controlled trials of homeopathy. *J Clin Epidemiol*, 1999; 52: 631–6.

(4) Linde K, et al. Are the clinical effects of homoeopathy placebo effects? A meta-analysis of placebo-controlled trials. *Lancet*, 1997; 350: 834–43.

(5) Kleijnen J, et al. Clinical trials of homeopathy. *Br Med J*, 1991; 302: 316–23.

Homeopathy trials revealing no difference from controls:

(1) Shang A, et al. Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy. *Lancet*, 2005; 366: 726–32.

It is increasingly clear that there are methodological complications using RCTs as the primary means by which to evaluate CAM modalities.[1]

It is wrong to consider that evidence published in the peer reviewed literature is the only standard of evidence that can be allowed, given that it is likely that the majority of published evidence (perhaps 60%) is false (see: Ioannidis JP. Why most published research findings are false. PLoS Med, 2005; 2(8): e124). As Prof John Ioannidis indicates (in the paper cited above), smaller trials published in the peer reviewed literature are particularly vulnerable to providing false conclusions about outcomes and these are typical of many trials in the CAM field given under-investment compared with, for example, pharmaceutical research.

[1] Mason S, Tovey P, Long AF. Evaluating complementary medicine: methodological challenges of randomised controlled trials. *BMJ.* 2002 Oct 12;325(7368): 832-4. Review. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1124333/*

- **Markers of benefit.** Given the Charity Commission's legal requirement to assess public benefit, scientifically assessed measures of benefit are of key importance. Clinical outcomes in terms of reduction of symptoms of disease or disease risk, for example, are far from the only markers of benefit, yet these are invariably the primary (or only) outcomes measured. These outcomes are rarely measured or interpreted from the patient's perspective.[2] Other key markers of benefit that could be measured using patient-reported surveys (see below) include patient satisfaction, quality of life, functional health (e.g. mobility, ease of movement), pain, emotional health, stress, etc.

- **Assessments of patient-reported outcomes** using patient surveys or questionnaire responses. Some of these methods of measuring patient-reported outcomes are validated, e.g. the Optum's Short-Form (e.g. SF-12)[3], the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)[4], and Bristol University's Measure Yourself Medical Outcome Profile or MYMOP2[5].

- **Surveys of patients or clients** using CAM and/or related services offered or endorsed by the organisation that demonstrate the patients or clients have perceived a benefit or net benefit. These surveys would be designed in such a way that they target a representative of the relevant population for which the work of the organisation is directed. The survey might involve, for example, a minimum of 30 individuals in the relevant population groups given than 30 is often the minimum number that yields statistically significant results. A wide range of factors might be the subject of questions in order to test the validity of the legal requirement for public benefit including: satisfaction with the services provided, quality of life improvement, improved functional health (e.g. mobility), pain reduction, improvement in the perceived function of any specific body system, improvement in symptoms of a named and diagnosed disease linked in time with the CAM intervention, increased mobility, improved mood, reduced depression or negative emotional state, education, knowledge gain, etc.

- **Reports from third parties or organisations** demonstrating positive benefit based on the type of factors discussed above in relation to surveys.

- **Reports from acknowledged, independent experts in a relevant CAM field**. These experts would typically be attached to a university or other recognised academic institution, but may also include qualified and experienced practitioners in the relevant CAM discipline who are acknowledged as such by their peers. These

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[2] Greenhalgh T, Snow R, Ryan S, Rees S, Salisbury H. Six 'biases' against patients and carers in evidence-based medicine. *BMC Med.* 2015; 13: 200.

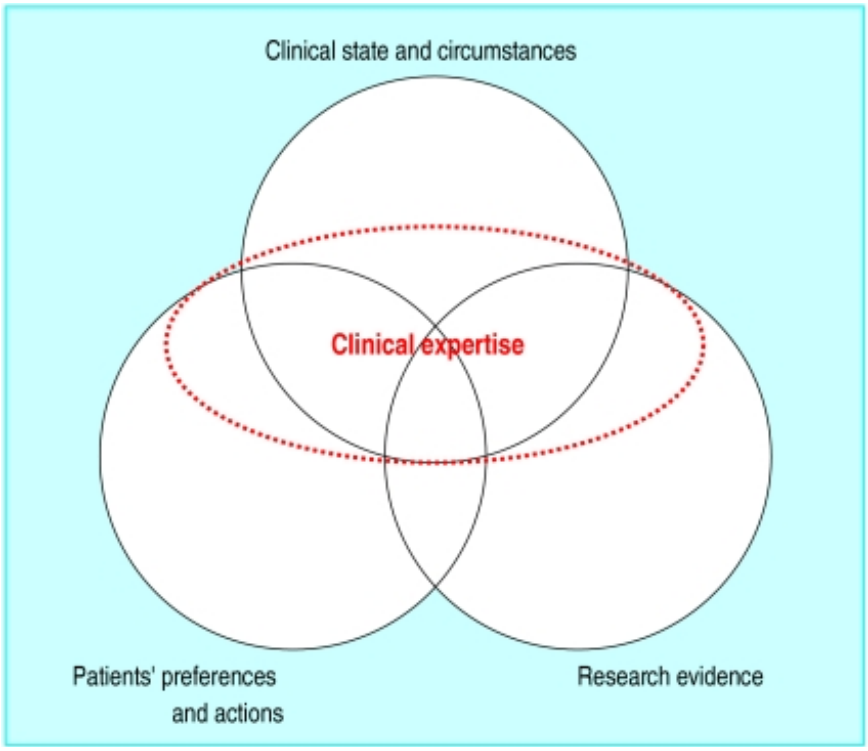
[3] Optum SF-12: *https://campaign.optum.com/optum-outcomes/what-we-do/health-surveys/sf-12v2-health-survey.html*

[4] Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS): *http://www2.warwick.ac.uk/fac/med/research/platform/wemwbs*.

[5] MYMOP (Measure Yourself Medical Outcome Profile): *http://www.bris.ac.uk/primaryhealthcare/resources/mymop/general-information*.

experts should in turn make reference to the peer reviewed literature and relevant clinical evidence, following the general principles of evidence-based medicine[6] or evidence-base practice.[7]

The importance of clinical expertise, and its interaction with research evidence, is made clear by Haynes *et al* in their *British Medical Journal* article (2002)[5] and is summarised in the figure derived from this paper, below:



- **Reports from associations or educational/training institutions** for practitioners of the relevant CAM modality. The associations and leaders that represent each CAM modality have extensive backgrounds, clinical expertise and knowledge of the effects of modalities in question and are in a good position to inform the Charity Commission of the public benefits (and any risks) associated with their modality. Equally, academic trainers relevant to each modality, usually highly experienced clinicians themselves, are also deeply familiar with the research evidence and clinical outcomes associated with the modality in question.

[6] Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ,* 1996; 312(7023): 71-2.

[7] Haynes RB, Devereaux PJ, Guyatt GH. Physicians' and patients' choices in evidence based practice. *BMJ.* 2002; 324(7350): 1350.

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?

General acceptance of a CAM therapy should absolutely not be a required criterion for evidence, for the reasons given in our response to Question 1. General acceptance dictates that the view has been held, relatively, for a long period of time and there is clear evidence in history that long-held views are not always true. This has recently been shown to be the case with the relationship between blood cholesterol and mortality risk[8], and the 30 years of public health policy advising the public (wrongly, and without credible or RCT evidence) to consume a low fat diet to reduce heart disease risk.[9]

Also, generally accepted evidence of a CAM therapy would necessitate that the relevant therapy is accepted by the mainstream medical community, when this community is itself highly subject to its own pre-determined views and biases.

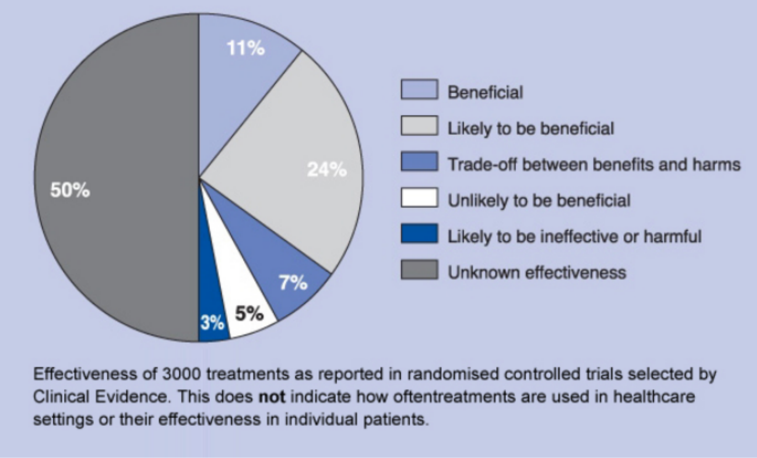
This phenomenon has been well documented by Dr Peter Gøtzsche, a Danish physician, medical researcher and leader of the Nordic Cochrane Center at Rigshospitalet in Copenhagen in his book, *Deadly Medicines and Organised Crime: How Big Pharma Has Corrupted Healthcare* (2013, London: Radcliffe Publishing/CRC Press, Taylor & Francis Group, 322 pp).[10] Dr Gøtzsche demonstrates that many drugs provide no benefit and are actively harmful. An analysis by *BMJ Clinical Evidence* of 3000 medical treatments for which RCTs have been conducted reveal that only 11% have been proven to have beneficial effects (Box 2). Fifty percent are of unknown effectiveness (Box 2).

[8] Ravnskov U, Diamond DM, Hama R, et al. Lack of an association or an inverse association between low-density-lipoprotein cholesterol and mortality in the elderly: a systematic review. *BMJ Open* 2016; 6: e010401.

[9] Harcombe Z, Baker JS, DiNicolantonio JJ, Grace F, Davies B. Evidence from randomised controlled trials does not support current dietary fat guidelines: a systematic review and meta-analysis. *Open Heart,* 2016; 3(2): e000409. http://openheart.bmj.com/content/3/2/e000409

[10] See review: Dickinson J. Deadly medicines and organised crime: How big pharma has corrupted healthcare. *Canadian Family Physician*, 2014; 60(4): 367-368. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4046551

BOX 2 – BMJ Clinical Evidence evaluation of efficacy of medical treatments supported by evidence from randomised trials



Effectiveness of 3000 treatments as reported in randomised controlled trials selected by Clinical Evidence. This does **not** indicate how oftentreatments are used in healthcare settings or their effectiveness in individual patients.

Source: http://clinicalevidence.bmj.com/x/set/static/cms/efficacy-categorisations.html

The principle of 'generally accepted' scientific evidence has been used in the implementation of the EU Nutrition and Health Claims Regulation for establishing authorised health claims in the EU (see Recitals 11, 18 and 26, and Articles 5.1(a), 5.1(b)(i), 5.1(b)(ii), 5.1(d), 6.1, 13.1(c)(i) and 13.4). In its evaluation of evidence, the European Food Safety Authority (EFSA) has issued positive opinions for only 259 health claims (out of over 5000 initially evaluated); see EU Register on Nutrition and Health Claims. This system has resulted in hundreds of plausible or credible claims, such as the benefits associated with consumption of essential amino acids, being rejected and now being 'non-authorised' throughout the EU.

Although it is a US case, we wish to draw the Charity Commission's attention to the successful case, *Alliance for Natural Health US vs Sebelius (786 F.Supp.2d 1 (D.D.C. 2011)* where the Alliance for Natural Health challenged the imposition of a ban on qualified health claims for the antioxidant status of vitamins C and E by the US Food & Drug Administration (FDA). The threshold required for making qualified health claims in the US is "significant scientific agreement" which is similar to the EU's "generally accepted scientific data" requirement established in Regulation 1924/2006. In summary, the District Court of Columbia found that evidence is rarely conclusive or significantly agreed. A ban on the health claims was regarded as an infringement of a manufacturer's First Amendment right to freedom of expression and the only legal requirement was for the credibility of the evidence. We believe, accordingly, that 'credible' evidence should be a sufficient threshold for the amount and quality of evidence required by the Charity Commission. Some examples of the type of credible evidence required are described in the answer to Question 1.

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

Conflicting and inconsistent evidence is the norm for any branch of the biomedical or healthcare sciences. There are many reasons for this, including biases in research methods, statistical analysis or publication leaning, the small size of studies, confounding factors in trials, and the lack of comparability between treatment and control groups.

Importantly, most evidence in the peer reviewed literature is based on outcomes for disease treatment based on evaluating changes in the clinical symptoms or biomarkers of disease. This is a very narrow interpretation of benefit, and the Charity Commission's legal remit to ensure a requirement for public benefit for organisation's seeking charitable status should not be limited to this narrow interpretation.

For example, if the effect of acupuncture on back pain is being evaluated, evidence for the acupuncture treatment reducing symptoms of pain in a study population should not be the only marker for benefit, as benefits other than pain reduction (sometimes referred to as non-specific effects)[11] are common in acupuncture treatments. If for example, those patients undergoing acupuncture also found themselves to be less depressed, more relaxed and/or with improved quality of life, factors that are unlikely to have been measured in most clinical trials, these would suggest public benefit especially if such effects were common place. Such 'non-specific' improvements in quality of life are commonly reported by many patients receiving CAM treatments, yet they are rarely measured. Studies very rarely cater for the patient's experience, yet this is crucial to the notion of benefit.

Trish Greenhalgh and colleagues (2015)[12] from the Nuffield Department of Primary Care Health Sciences, University of Oxford, identified six different biases relating to evidence-based medicine (EBM) that impact both patients and carers, these being:

- Most published research had minimal patient input
- EBM's hierarchy of evidence tends to devalue the patient or carer experience
- EBM conflates patient-centredness with use of decision-making tools
- Power imbalances may suppress the patient's voice
- EBM over-emphasises the clinical consultation
- EBM is concerned mainly with people who seek (and can access) care

Many of these issues relate strongly to patients receiving healthcare support in a CAM setting. These concerns may be more valid and relevant than a classical EBM view in relation to CAM therapies.

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[11] Williams CM, Kamper SJ. Non-specific effects of acupuncture – Does the 'placebo' effect play an important role? *Br J Sports Med* 2012; 46: 578-579. http://bjsm.bmj.com/content/46/8/578.info

[12] Greenhalgh T, Snow R, Ryan S, Rees S, Salisbury H. Six 'biases' against patients and carers in evidence-based medicine. *BMC Med.* 2015; 13: 200.

Two examples from mainstream medicine that reveal the common nature of conflicting or inconsistent evidence are considered briefly below:

Example 1: Use of mammography for early detection of breast cancer

The Nordic group of the Cochrane Collaboration argue that current evidence suggests that mammography screening may cause more harm than benefit.

The authors *state*: "*More recent studies suggest that mammography screening may no longer be effective in reducing the risk of dying from breast cancer. Screening produces patients with breast cancer from among healthy women who would never have developed symptoms of breast cancer. Treatment of these healthy women increases their risk of dying, e.g. from heart disease and cancer*."

By contrast, the National Health Service (NHS) advises that mammography reduces the risk of breast cancer. NHS Choices *states*: "*About one in eight women in the UK are diagnosed with breast cancer during their lifetime. There's a good chance of recovery if it's detected in its early stages. Breast screening aims to find breast cancers early. It uses an X-ray test called a mammogram that can spot cancers when they are too small to see or feel…..Most experts agree that regular breast screening is beneficial in identifying breast cancer early. The earlier the condition is found, the better the chances of surviving it*."

Example 2: use of statin drugs for primary prevention of cardiovascular disease

The NHS recommends statins for all age groups. NHS Choices states: "*In most cases, treatment with statins continues for life, as stopping the medication causes your cholesterol to return to a high level within a few weeks*."

This presupposes that high cholesterol is a risk factor for mortality. This 'generally accepted' view is increasingly contested.

For example, in a recent review by Ravnskov *et al* of cohort studies involving nearly 70,000 patients, published in BMJ Open in 2016,[13] the authors found an inverse relationship between high LDL cholesterol in patients over 60 years old. The authors *concluded*: "*This finding is inconsistent with the cholesterol hypothesis (ie, that cholesterol, particularly LDL-C, is inherently atherogenic). Since elderly people with high LDL-C live as long or longer than those with low LDL-C, our analysis provides reason to question the validity of the cholesterol hypothesis. Our review provides the basis for more research about the cause of atherosclerosis and CVD and also for a re-evaluation of the guidelines for cardiovascular prevention, in particular because the benefits from statin treatment have been exaggerated*."

[13] Ravnskov U, Diamond DM, Hama R, et al. Lack of an association or an inverse association between low-density-lipoprotein cholesterol and mortality in the elderly: a systematic review. *BMJ Open* 2016; 6: e010401.

Conclusion

In both of the above cases, the experts that made different interpretations of the available evidence and then drew opposing conclusions, were experts in the same field, i.e. mammography/oncology and statins/cardiovascular disease, respectively.

By contrast, most of the claims of inconsistent or inconclusive evidence that relate to CAM therapies come from individuals and organisations who, or which are, not expert in the relevant CAM field. While the critics may be experts in a given scientific or even medical field, it is crucial that the Charity Commission considers the relevance and applicability of these experts' backgrounds.

For example, Simon Singh PhD, physicist and Chairman of The Good Thinking Society, has no clinical background in the CAM therapies about which he has been vehemently critical, such as chiropractic or homeopathy. In his criticisms, Dr Singh does not take into account any evidence of patient experience, and he has no clinical experience himself. He only has recourse to the peer review and then interprets evidence selectively to support his view that the therapy in question is ineffective. The very existence and popularity of a given therapy, it could be argued, is evidence that members of the public gain benefit from it given that they are prepared to pay for delivery of clinical services.

As the above two examples demonstrate, inconclusive and conflicting data is probably more the norm rather than the exception, regardless of whether mainstream medicine or CAM therapies are considered. This situation is likely a function of the lack of precision of the scientific methodologies used in measuring multi-factor interventions, the difficulties inherent in measuring the real world as opposed to an artificial experimental setting typical of RCTs, and the inherent variability of individuals within study populations, each with genotypic and phenotypic characteristics that are expressions of hugely complex and unique gene-environment interactions. The smaller the study, the more these sources of variation will contribute to 'noise' in the data.

It is relevant to note that one of the greatest UK-based critics of CAM therapies was an associate of Simon Singh, the now retired Prof Edzard Ernst, also a leading member of the UK Skeptic movement. Prof Ernst's research group at Peninsula Medical School at the University of Exeter published over 1100 papers in a 16-year period. Partially because of the book he co-wrote with Singh, *Trick or Treatment: Alternative Medicine on Trial* (2008, W. Norton & Company, 352 pp), Prof Singh decided to analyse the net outcome of his own group's research in an article in the *Pulse* journal entitled "In self-defence" (12 April 2010).[14] In his article, Ernst states that his group's research could be categorised as 53% positive findings, 40% neutral and 7% negative. This might be contrasted with the *BMJ Clinical Evidence* categorisations of medical interventions (see Box 2), viz: 11% beneficial, 24% likely to be beneficial, 50% unknown effectiveness, 5% unlikely to be beneficial, 7% trade-off between benefits and harms, and 3% likely to be ineffective and harmful.

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[14] Ernst E, "In self-defence". *Pulse*, 12 April 2010: *http://www.pulsetoday.co.uk/in-self-defence/11029474.article*.

Therefore, we recommend that the Charity Commission recognise that if experts in the same fields often are unable to agree based on conflicting or inconsistent evidence, the Charity Commission is unlikely to be in a position to act as arbiter on these matters. Such evaluation should more properly viewed as a scientific matter and not one that is within the Charity Commission's jurisdiction.

The Charity Commission, as has been suggested in answers to previous questions (above), should rely only on credible or plausible evidence, and that evidence might be derived from patients or recipients of the treatments, their professional bodies or clinical experts in relevant CAM field, given that patient experience is the most direct measure of benefit to the recipient.

In a systematic review by Cathal Doyle *et al* (2013), emerging from a collaboration between Chelsea and Westminster Hospital and Imperial College London, patient experience was found to be "*positively associated with clinical effectiveness and patient safety, and support the case for the inclusion of patient experience as one of the central pillars of quality in healthcare*."[15]

Moreover, the late Prof Sackett, the originator of the concept of evidence-based medicine and leader of the Evidence Based Medicine Working Group[16] had already reason to complain, via the *British Medical Journal* in 1996, that clinical experience — a central pillar of EBM along with high quality published evidence – had already been largely ignored by proponents of EBM.[17]

[15] Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open.* 2013; 3(1). pii: e001570.

[16] Evidence-Based Medicine Working Group. Evidence-based medicine. A new approach to teaching the practice of medicine. *JAMA,* 1992; 268(17): 2420-5.

[17] Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ,* 1996; 312(7023): 71-2.

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?

The most important source of data for evaluating benefit is patient experience (e.g. self-reported) as this is a direct measure of benefit by the recipient, but, as discussed in answers to previous questions, this is rarely measured in trials or studies.

In the case of CAM organisations which use or promote complementary therapies that are used alongside conventional treatments, the same requirement to demonstrate benefit from the combined therapy should apply as compared with when a single, alternative CAM therapy is used.

It is important for the Charity Commission to recognise that most CAM practitioners utilise a multi-modality approach, in which concomitant advice is given alongside the provision of a treatment associated with one or more individual CAM modalities. For example, a medical herbalist or osteopath will invariably provide advice to a client about improving diet and lifestyle, such support being much more likely than in the case of primary care in a GP surgery where the typical 10-minute consultation provides a major limitation, along with lack of relevant training of doctors. Assessment of patient experience is again the best way of assessing the net effect of combination therapies and approaches.

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?

Legally, CAM therapies cannot claim to treat or prevent disease, under both EU and UK laws.

The EU Medicines Directive (2001/83/EC, as amended) has two limbs, the first dealing with presentation of medicinal products, the second, their function, expressed in Article 1.2, as follows:

> "(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
>
> (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis."

Given that both the relief of symptoms and cure of disease are exclusively the domain of medicinal products and authorised healthcare professionals such as medical doctors, these cannot generally be applied to CAM modalities that are practiced in the main by practitioners specifically trained in their respective CAM therapies. These CAM therapies are, for complex reasons, not statutorily recognised, with the exception of chiropractic and osteopathy, and they therefore fall outside the domain of mainstream medicine.[18]

The EU Medicines Directive was transposed into UK statutory instruments, in the form of:

- The Medicines (Codification Amendments Etc.) Regulations 2002 S.I. n° 236 of 2002
- The Medicines for Human Use (Fees Amendments) Regulations 2006
- The Medicines for Human Use (National Rules for Homeopathic Products) Regulations 2006

The UK statute, Human Medicines Regulations 2012[19] maintains in Section 3(6) special provisions for herbalists to assemble and supply unregistered herbal medicines supplied on the basis of a one-to-one consultation with the person receiving it.

Based on the fact that much of the existing, published evidence is restricted to disease treatments or cures, it is all the more important that patient experience becomes the predominant assessment criterion.

We would like to summarise the most salient points in our consultation response, while providing some additional clarification:

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[18] NHS Choices - Complementary and alternative medicine: *http://www.nhs.uk/Livewell/complementary-alternative-medicine/Pages/complementary-alternative-medicines.aspx*.

[19] Human Medicines Regulations 2012: *http://www.legislation.gov.uk/uksi/2012/1916/pdfs/uksi_20121916_en.pdf*.

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

1. Evidence in the peer review is generally related to clinical symptoms and these are just one aspect relating to benefit. Benefit must be able to be construed in the widest, most holistic sense, in ways that are relevant to the target population of the organisation's work.

2. Evidence of effectiveness, that relates to the effect in the real world (efficacy relates only to experimental conditions such as those used in RCTs), is often the result of multiple factors, many of which are not measured in a RCT, such as regression to the mean, Hawthorne effect, placebo effect, psycho-social factors, concomitant treatments, etc.

3. Data from biomedical research is nearly always inconclusive or conflicting, and the Charity Commission should not be placed in a position to act as arbiter on such matters given that even experts in their respective areas cannot necessarily agree in areas where there is less available data or controversy (e.g. dietary fats/mortality, statins/cholesterol, mammography/breast cancer).

4. It is important that evidence of benefit is credible or plausible, rather than being conclusive, given that scientific data on biomedical issues is so rarely conclusive. This is largely because cause and effect relationships are very difficult to establish, as demonstrated by the number of years of research required to unequivocally link tobacco smoking to lung cancer.[20]

5. The single most important measure of benefit should be patient experience and there are several self-reporting survey methods (including validated ones) that are able to measure patient experience.

6. A diverse range of other methods of credible evidence have been discussed in the present consultation response. The legal requirement for public benefit should include consideration of the scope of the population that could be targeted by the organisation's work, as well as the holistic evidence of benefit seen from the perspective, where possible, of the targeted persons.

7. A "generally accepted" evidence approach is unacceptable because it preferentially supports long-standing approaches that are endorsed by the medical mainstream, while ignoring emerging evidence or evidence relevant to minority or disadvantaged groups.

[20] Hecht SS. Cigarette smoking and lung cancer: chemical mechanisms and approaches to prevention. *Lancet Oncol.* 2002 Aug;3(8):461-9. Review.

8. The Charity Commission should generally not limit its evaluation of CAM therapies to those shown to either improve symptoms of disease or to cure them, as these are presently regarded as the legal domain of mainstream medicine and authorised healthcare professionals, as established in EU and UK law.

Should the Charity Commission have any queries emanating from the our responses to the consultation, we would be more than happy to engage in further consultation or to attend meetings on behalf of those we represent.

Robert Verkerk PhD
Executive and scientific director
19 May 2017