the Nightingale Collaboration

Response to:

Accreditation standards for organisations that hold voluntary registers for health and social care occupations

Draft for consultation

Alan Henness
Director

Maria MacLachlan
Director

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www.nightingale-collaboration.org
info@nightingale-collaboration.org

Introduction

The Nightingale Collaboration[1] *challenges questionable claims made to the public by healthcare practitioners on their websites, in adverts and in their promotional and sales materials by bringing these to the attention of the appropriate regulatory bodies. The vast majority of these claims are made by practitioners of alternative therapies.*

We also strive to ensure that organisations representing healthcare practitioners have robust codes of conduct for their members that protect the public and that these are enforced.

We note that the aims of the CHRE are:

> …to promote the health, safety and well-being of patients and other members of the public and to be a strong, independent voice for patients in the regulation of health professionals throughout the UK.

It cannot be emphasised enough that the overriding concern for the CHRE is in the protection of the public and an independent voice for patients — we believe it is right and essential that everything the CHRE does must align with this aim.

It is therefore disappointing to see that the proposed criteria and standards for the Accreditation Register would currently appear to allow registers of occupations that would compromise this laudable aim.

Several of the trade bodies and other organisations that have so far expressed an interest in joining the Register represent numerous alternative (or 'complementary') therapies. The single characteristic that separates them from others is their lack of robust evidence of efficacy or effectiveness. Also, most of these therapies have no plausible mechanism of action.

For example, therapies such as homeopathy, reiki and crystal healing have no credible scientific evidence to substantiate any claim that they are effective.

Common problems with many of the trials of alternative therapies that have been conducted include poor methodology and dubious research ethics.[2]

However, information on the evidence-base for some alternative therapies is easily found.[3] In particular, a comprehensive report on the evidence for homeopathy was published by the House of Commons Science and Technology Committee.[4] It concluded that there was no credible scientific evidence for homeopathy and recommended that it not be funded by the Government.

There is no doubt that many customers of alternative therapists believe they have gained some benefit from the therapeutic encounter. These benefits might be relaxation or a feeling of relief that someone has taken the time to listen to them.

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[1] "The Nightingale Collaboration", n.d., http://www.nightingale-collaboration.org/.

[2] Edzard Ernst, "Research Ethics in CAM," *Focus on Alternative and Complementary Therapies* 10, no. 3 (2005): 171–176.

[3] E Ernst, Max H Pittler, and Barbara Wider, *The desktop guide to complementary and alternative medicine : an evidence-based approach* ([Edinburgh]: Mosby Elsevier, 2006).

[4] House of Commons Science and Technology Committee, *Evidence Check 2: Homeopathy*, Fourth Report of Session 2009–10, n.d., http://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/45.pdf.

This is acknowledged and it is unlikely that a consumer would be misled if all that was claimed was that the encounter could contribute positive benefits in terms of relaxation or overall 'wellbeing'.

However, we are well aware that many therapists go far beyond this and claim positive resolutions to medical conditions. We believe this is misleading and potentially dangerous.

Robust evidence

By robust evidence, we mean evidence that is derived from repeatable, fair and independent trials that have been published in peer-reviewed scientific journals.

In considering this, the consensus of scientific opinion on the best available evidence must be given due weight.

We appreciate that this can sometimes be difficult to comprehensively determine, but good indicators of what therapy might have a good evidence base are meta-analyses published in peer-reviewed scientific journals. The Cochrane Collaboration is an excellent source of independent systematic reviews and meta-analyses of many alternative therapies.[5]

If the above criteria are not met, there is a grave danger that evidence gathered from unsound or biased tests, single case studies or even anecdotes could lead to unsafe or ineffective treatments being administered to the public who may be unaware of this lack of sound evidence.

This cannot be in the public interest and certainly not a situation a Government body such as the CHRE should be seen to support, validate in any way or lend any credibility to.

Also, a therapy that cannot show any clinically proven therapeutic benefit cannot be considered to be a 'health occupation' or a 'social care occupation' and this must exclude them from being considered for Accredited Register status.

Specific and non-specific effects

Many alternative therapies are not able to show robust evidence for specific benefits, ie a benefit deriving from the actual treatment administered.

It is widely recognised that the encounter with an alternative therapist can sometimes bring with it a non-specific benefit, ie one not directly related to the treatment itself.

These benefits might be a feeling of relaxation or relief that someone has taken the time to listen to them and there is little doubt that some customers are helped by this.[6]

This is acknowledged and it is unlikely that a consumer would be misled if all that was claimed was that the encounter could contribute positive benefits in terms of relaxation or overall 'wellbeing'.

However, this does not mitigate the need for robust evidence for the *specific* effects of that treatment.

We will return to the importance of understanding the differences between specific and non-specific effects later.

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[5] "The Cochrane Collaboration | Working Together to Provide the Best Evidence for Health Care", n.d., http://www.cochrane.org/.

[6] "CM Practitioners Have Better Bedside Manner Than GPs," *Focus on Alternative and Complementary Therapies* 2, no. 1 (1997): 7–7.

Mechanism of action

Therapies such as homeopathy, reiki and crystal healing have no plausible mechanism of action.

We have no doubt that some of their proponents believe they have an hypothesis of how it might work, but it is a general feature of alternative therapies that these hypotheses are not scientifically credible and would not be considered plausible by someone well versed in the sciences of physics, chemistry, biology, medicine, etc.

Some of the beliefs commonly encountered in purported explanations for alternative therapies include qi (or chi), meridians, auras, 'vital force', 'life force' or 'biofield energy'.

Explanations of medical conditions frequently involve unscientific constructs such as miasms, various imbalances in undefined 'energies', blocked meridians, blocked auras, emotional traumas, humours and vertebral subluxation complexes. None of these have any basis in science and contravene well-established principles of science and are no more than simplistic pre-scientific and pseudo scientific notions that do not align with the known workings of the human body.

Even for, say, acupuncture, where there may be some tentative evidence of efficacy for a few limited conditions, it is clear that the purported mechanism of action (unblocking qi or meridians) have no foundation in biology. More prosaic mechanisms frequently provide an explanation of any reported effect.

Unfortunately, many proponents of these therapies have evolved elaborate explanations that might sound plausible to someone who does not have a basic grounding in physics, chemistry and biology and they may find these explanations credible and persuasive, leading them to believe the therapy is legitimate.

To give practitioners of any such therapy the mantle of official regulation is to lend credence to it and this can only further mislead the public.

Harms

Many alternative therapists claim that their therapy is entirely risk-free, or at least so low risk that the potential for harm is not even worth considering or even worth mentioning to customers.

One of the problems is that there are very few data on which these therapists could base such an assertion because there are no mechanisms in place to collect those data. We have no doubt that, even if there was a voluntary mechanism in place, reporting levels would be extremely low.

It is also documented that the completeness of safety reporting in reports of complementary and alternative medicine trials is largely inadequate.[7]

Additionally, if there is no plausible mechanism of action, it is impossible to assess and quantify the risks associated with that therapy.

Overall, we conclude that the harms of alternative therapies are generally not known and not well understood.

However, consideration of the effects of this need to be further considered.

There are two manifestations of possible harms caused by alternative therapies: direct and indirect harms.

[7] Lucy-Ann Turner et al., "An Evaluation of the Completeness of Safety Reporting in Reports of Complementary and Alternative Medicine Trials," *BMC Complementary and Alternative Medicine* 11, no. 1 (2011): 67.

Direct harms

We are aware that some alternative therapies are relatively harmless in themselves.

However, there are direct harms associated with some (including many that are covered by the registers of organisations that have already expressed an interest in the Accredited Register scheme): [8]

Therapy	Possible direct harms
acupuncture	Pneumothorax, infections, drowsiness, bleeding, bruising
aromatherapy	Phototoxic reactions, possible carcinogens, allergic reactions, nausea, headaches
chelation	Renal failure, arrhythmias, bone marrow depression, convulsions, respiratory arrest
colonic irrigation	Infections, bowel perforation, electrolyte imbalance
homeopathy	Some unlicensed homeopathic medicines contain significant quantities of substances that could endanger health
naturopathy	Drug interactions
reflexology	Fatigue, changes in micturition or bowel function, allergy to lubricants

Indirect harms

Although some alternative therapies — such as crystal therapy — have no obvious *direct* harms, there are many indirect harms that can be encountered. These include a general negative attitude to conventional medicine, particularly vaccinations,[9] [10] but covering a definite bias against doctors and treatments that are backed by a good level of robust evidence.

This frequently comes from a flawed understanding of science and it is easy to see how this can happen, given the erroneous explanations of mechanisms of action and disease mechanisms associated with many alternative therapies.

This is a serious matter: although it is difficult to quantify the extent of these beliefs even a cursory search of websites of alternative therapists will confirm the extent and depth of them.

Other indirect harms include psychologic harm related to unnecessary treatment, psychologic harm caused by exposure to these false beliefs, and financial harm due to unnecessary treatment.

[8] Ernst, Pittler, and Wider, *The desktop guide to complementary and alternative medicine*, 358.

[9] Edzard Ernst, "Complementary and Alternative Medicine's Opposition to Measles Immunisation Continues," *Focus on Alternative and Complementary Therapies* 16, no. 2 (2011): 110–114.

[10] Katja Schmidt and Edzard Ernst, "Welcome to the Lion's Den – CAM Therapists and Immunisations," *Focus on Alternative and Complementary Therapies* 10, no. 2 (2005): 98–100.

Consequences

What are the consequences of these harms?

We are aware of several high-profile cases of serious injury and death as a direct result of reliance on alternative therapies rather than on conventional medical care.[11]

Even if such tragic events are rare, there is no mechanism by which the public, alternative therapists or organisations can independently gather information about even minor harms. This means that there is no mechanism of learning from these events and therefore no means of future harm reduction. This cannot be good for public safety and puts future customers at risk.

Again, even if such serious harms are rare, the consequences of the attitudes of many alternative therapists towards conventional medicine could result in a customer delaying or forgoing possibly urgently needed medical advice and treatment.

If a case of negligence against a registrant of an organisation on the Accredited Register ever reached court, we understand that if there are no established data on risks, then the standard of Bolam would apply, ie "a practice accepted as proper by a responsible body of medical men skilled in that particular field"[12]. Even though alternative therapies are not medical *per se*, we believe the superficial similarities would lead to a comparison. This would leave a defendant in such a case possibly being supported by other therapists who are part of the same belief system of that alternative therapy, not grounded in science.

We believe that this can do nothing but damage the credibility and public confidence of the organisation that accredited the alternative therapy organisation.

We cannot understand why a responsible Government body would wish to become associated with these therapies, particularly as we see no mechanism by which being on an Accredited Register encourages or ensures improvements in safety — and indeed, because of the nature of many of these therapies — no method by which attitudes towards conventional medicine could be changed.

Indeed, we can visualise many registrants and their Accredited organisations taking impetus from their Government-approved accreditation and further developing and promulgating their unscientific views to the detriment of all.

Risk-benefit

The risk-benefit analysis of a treatment is an important consideration if a consumer is to make an informed choice and exercise informed consent.

It is not possible to consider *just* the benefits or *just* the risk s— one has to be weighed against the other.

In considering the risk-benefit analysis, the specific effects must first be considered.

[11] For example, *RECORD OF INVESTIGATION INTO DEATH of Penelope Dingle (nee Brown)*, n.d., http://www.safetyandquality.health.wa.gov.au/docs/mortality_review/inquest_finding/Dingle_Finding.pdf.

[12] *Bolam v Friern HMC [1957] 1 WLR 582* (n.d.).

This can be summarised:

	No benefit from specific effects	Some benefit from specific effects
No direct harm	0	+
Some possible direct harm	–	~

If there is no benefit from the specific effects of a treatment, then, regardless of any risk, the risk-benefit analysis cannot be favourable.

If there are risks involved, a risk-benefit analysis becomes decidedly negative (ie it does more harm than good).

Where there is good evidence for some benefit from specific effects and the direct harms are known to be negligible, then, overall, there is likely to be a positive risk-benefit.

Where there is no good evidence from specific effects and either negligible or known definite risks, the risk-benefit analysis cannot be positive.

As we have said above, there is very little positive evidence for the vast majority of alternative therapies. However, where there might be some benefit, but there are also some risks, a decision has to be made by the customer, weighing up one against the other.

The decision is that individual's to make, but this can only be made in any meaningful sense if all the information about both benefit and risks is fully available before consenting to a treatment.

With alternative therapies, we believe that customers and potential customers are most often told neither about the lack of good evidence for specific benefits nor given any information about possible risks.

Thus, no meaningful consent can be given.

Regardless of the outcome of the analysis of specific benefits against risk of harms, with many alternative therapies automatically come the indirect harms as we outlined above.

Possibly the greatest potential for harm is in the erroneous beliefs about conventional medicine and doctors.

Eligibility

In view of the above, we strongly recommend that a mandatory eligibility requirements for any organisation includes:

1. Robust scientific evidence base for the specific effects of the therapy.
2. A plausible mechanism of action.
3. A comprehensive understanding of the risks.

Without these, the public will be put at increased risk by inclusion in what will be seen as a Government-accredited register.

Comments on the standards

We comment on various paragraphs of the standards below to highlight our specific concerns and how the concerns we highlighted above interact with the different eligibility criteria and standards.

A. Eligibility criteria

> A.1 The organisation holds a voluntary register for people working within health and social care (having regard to the definition of health set out in the Health and Social Care Act 2012

This talks of those working within 'health and social care'. Since most alternative therapies have no robust evidence base, it would be wrong to describe them as working in health. This criterion would, rightly, exclude alternative therapy organisations but we recommend that the standards make it clear that it is open only to health professionals.

> A.2 The organisation can demonstrate that it is committed to protecting the public and promoting public confidence in the profession or occupation it registers

We reiterate that the public cannot be protected if there is no proven significant risk-benefit for an alternative therapy.

But there is a more serious problem with the proposal that the organisation must promote confidence in the profession/occupation it registers.

We do not see it as beneficial for a regulator to maintain public confidence in the occupations of alternative therapists for the reasons we set out above, *viz*, that they are not founded in evidence and science and therefore not entitled to any professional standing with the public.

We do, however, see it as a paramount duty of the regulator to maintain public confidence in the regulator itself. We believe that public confidence in an occupation is the indirect consequence of good, impartial and transparent regulation.

Indeed, we do not see how public confidence in a regulator could even be accurately or meaningfully measured nor what steps a regulator might be expected to take to fulfil this duty that would not put it in conflict with its other duties.

We therefore believe that any such action would raise serious concerns about conflicts of interest and impartiality and may have the concomitant effect of undermining public confidence in the regulator itself.

If, for whatever reason, the standing of an occupation as a whole is diminished by its registrants or otherwise, then it would not be in the public interest for the regulator to intervene in any way and become involved in rehabilitating the profession in the eyes of the public.

The regulator would, of course, be involved in dealing with any complaints that may arise from such a situation, but this must, as always, be done with complete impartially and transparency. This is the time at which the independence of the regulator may be tested to the extreme and any conflicts of interest must not affect its judgment nor be seen to affect its judgment.

A.4 The organisation has a good understanding of the nature and extent of risks posed by the discipline (or disciplines) practiced by its registrants and has taken reasonable action to address them

It is not clear how the CHRE could ever determine that an organisation has a good understanding of the nature of these risks. We see no indication that many alternative therapists or their trade bodies even acknowledge the existence of any risks whatsoever. This leaves consumers potentially vulnerable.

A.5 The organisation is able to cover its legal liabilities with respect to any disciplinary action it takes against one of its registrants

It is not clear how this could ever be determined by the CHRE, particularly if direct and indirect harms have not been properly quantified and assessed.

It is also not clear what the CHRE's liability to any action brought against a registrant on an Accredited Register would be and how the CHRE could possibly isolate itself from any potential legal action. Even if the CHRE believed it was not responsible for providing legitimacy to an organisation or its registrants, it could still be cited in legal action and may have to defend its position in court proceedings.

A worst-case scenario would be the death or serious injury of a customer of a registrant on an Accredited Register. It seems entirely probable that anyone wanting action taken for compensation would pursue the CHRE as well as the individual and the organisation if it was shown that the treatments had no basis in robust evidence nor any independent safety assessment. This could seriously undermine the credibility of the CHRE in the eyes of the public as a Government body empowered to promote the health, safety and well-being of the public.

A.6 The organisation can demonstrate that it is respected within its field

It is not clear how this could ever be determined by the CHRE, particularly given the nature of the beliefs systems surrounding many alternative therapies.

A.7 The organisation can demonstrate that there either is a sound knowledge base underpinning the profession or it is developing one and makes that explicit to the public.

This talks about a 'knowledge base' but not an 'evidence base'. Many alternative therapists may well believe there to be a 'sound knowledge base' for their therapy, but, because of the nature of those beliefs, it is really a scientifically unsound knowledge base.

We are concerned that, in interpreting this standard, the CHRE may be disposed to allow registers of practitioners of such unscientific therapies to become Accredited Registers.

Giving these unscientific therapies the credence that having CHRE/Government Accredited Register status will, we believe, inevitably bring, endangers the public.

We therefore strongly recommend that this standard be re-written to state that a sound scientific evidence base is required to underpin all therapies. This would include a scientifically plausible mechanism of action, a robust evidence base for its specific effects and a sound understanding of the risks.

If a profession is still developing that sound knowledge, we cannot see how consumers can possibly be protected when subjected to a treatment by practitioners who haven't even yet got

that 'sound knowledge base'. The precedence should be clear: obtain the evidence base before allowing the legitimacy of Accredited Register status.

B. Governance

B.1 The organisation ensures that the governance of its registration function promotes the safety and well-being of consumers and the public, enhances confidence in its profession and places the best interests of the public before those of its profession

As we have said above, we do not believe that many alternative therapy organisations have any substantive awareness of the risks associated with their therapy.

As we said in our comments for standard A.2, we do not believe it is in the public interest for a regulator to be concerned with the public's confidence in the profession/occupation. To do so can only undermine the public's confidence in the regulator and in the CHRE.

We believe that many alternative therapy organisations, including some of the ones that have already expressed an interest in the Accredited Register, have aims of promoting the interests of their members and are, essentially, trade bodies. It is difficult to see how such an organisation can be expected to place the best interests of the public before those of its members. We believe there will always be significant conflicts of interest and we cannot see how this aligns with the CHRE's stated aims.

Many registrants will have close and sometimes intimate contact with members of the public, including vulnerable adults and children. This power relationship can be abused and appropriate steps must be taken to minimise the risk to the public.

We therefore strongly recommend that all registrants are subject to an Enhanced Criminal Records Bureau Check.[13]

B.2 Governance is carried out in accordance with recognised principles of good practice

It is not clear what these recognised principles of good practice are and we recommend that they be explicitly stated along with details of the means by which the CHRE will ensure Accredited Register organisations follow them.

B.4 The organisation engages with relevant stakeholders and works in partnership with other bodies to promote and protect the health, safety and well-being of consumers

Given what we said above about the frequent lack of a sound evidence base for alternative therapies, we cannot see how organisations of practitioners of these therapies could possibly promote and protect the health, safety and well-being of consumers.

Also, given the frequent antipathy held for conventional medicine and its practitioners by alternative therapists, we foresee many instances where the public are put a risk by a reluctance or refusal to suggest to a customer that they might need proper medical help. Indeed, few alternative therapists will be qualified to offer such an opinion and this may cause customers to delay seeking proper medical advice. Such situations may be exacerbated by a registrant's belief in their therapy and in their own abilities and no understanding of the limits of either.

[13] "Criminal Records Bureau", n.d., http://www.homeoffice.gov.uk/agencies-public-bodies/crb/.

This is evidenced by the many Advertising Standards Authority adjudications against alternative therapists for claims about their abilities to cure/help/alleviate medical conditions when they did not hold the robust evidence required to substantiate those claims.[14]

C. Setting standards for registrants

C.1 The organisation promotes high standards of personal behaviour, technical competence, and good business practice (including financial practice, advertising and customer service)

It is difficult to see how technical competence in, say, crystal healing or homeopathy, could be measured nor how an organisation could promote a high standard of it and we hope that this will be used to disallow organisations of alternative therapies from being admitted to the Accredited Register.

We understand the need for organisations and its members to abide by good advertising practice, but it is essential that the required standard is stated.

It is a requirement for all advertising (that falls within its remit[15])to comply with the Advertising Standard Authority's CAP Code[16] and we strongly recommend that abiding by this and other ASA guidance is specifically mandatory by the standards.

We also recommend that it a requirement of the standard that each organisation publishes advertising guidance on their website that they require members to follow and that any breach of that guidance or the publication of an adjudication or informally resolved complaint by the ASA is automatically investigated as a breach of the organisation's Code of Conduct and Ethics and dealt with appropriately under its Disciplinary Procedure.

We also recommend that, in the interests of ensuring the health, safety and well-being of customers and other members of the public, the organisation be required to monitor their members' websites and take appropriate action to ensure compliance with the guidance and CAP Code.

We also recommend that the standards include a specific prohibition on any registrant from using the title 'Dr' or the prefix 'Doctor' or otherwise represent themselves as a qualified medical practitioner at any time unless they are also registered with the General Medical Council.

We further recommend that the standards specifically prohibit any member from providing any treatment or service that they are not qualified to provide.

We also see a difficulty where a registrant provides a treatment or service other than that covered by the organisation of which they are a member. For example, a registrant could be a member of an organisation of homeopaths, but that member may also provide, say, acupuncture. If a problem arose with that treatment, we can see difficulties in a customer pursuing a complaint. This also arises in the case of an organisation that registers members of a number of different therapies.

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[14] For example, "ASA Adjudication on Ainsworths (London) Ltd - Advertising Standards Authority", n.d., http://asa.org.uk/ASA-action/Adjudications/2011/7/Ainsworths-(London)-Ltd/SHP_ADJ_148070.aspx.

[15] Advertising Standards Authority, "What We Regulate", n.d., http://asa.org.uk/Regulation-Explained/What-we-cover.aspx.

[16] "CAP - Committee of Advertising Practice", n.d., http://cap.org.uk/.

We urge the CHRE to consider the implications of such events and put in place appropriate standards to ensure that the public are protected and have an appropriate means of pursuing a complaint.

C.2 The organisation promotes ethical practice

We do not believe it is ethical for a therapist to mislead a customer into thinking that the therapy they offer can help/treat/cure/alleviate conditions that there is no robust evidence for.

Even if therapists are aware that their therapy is no more than a placebo, it cannot be ethical to not make customers aware that this is the case.

We therefore believe that most alternative therapy organisations cannot possibly abide by this requirement.

C.3 The organisation takes account of risks associated with the practice of its registrants

See previous comments on risks and harms.

C.4 The organisation bases its standards of competence upon a defined body of knowledge

See our comments on standard A.7.

C.6 The organisation encourages, where relevant, registrants to act as leaders within their communities to promote the health, safety and wellbeing of the public

Since there is little evidence that alternative therapies can promote the health, safety and wellbeing of the public, we believe that this standard, will, rightly, exclude practitioners of most alternative therapies.

C.7 The organisation keeps under review and evaluates its standards, considering whether they are achieving positive outcomes for consumers.

There is no doubt that some customers of alternative therapists do believe the treatment they were given has benefitted them. However, whilst customer satisfaction is important, this cannot be used as a surrogate for robust scientific evidence that the treatments are efficacious.

We also question how positive outcomes could be measured unless there are independent metrics of clinical outcomes, rather than just customer satisfaction.

D. Education and training

D.1 The organisation requires its registrants to successfully complete approved training that has been independently assessed and meets recognised quality assurance standards

It is difficult to see how training in, say, crystal healing or homeopathy, could possibly be assessed to any meaningful degree by any organisation that is truly independent.

Similarly, whilst it may be possible to have quality assurance standards that measure, say, the amount of teaching time, we cannot see how there can be any meaningful quality assurance standards of something that is inherently pseudo scientific.

> D.2 Where an organisation permits a vocational entry route, registrants successfully complete an independent assessment that meets recognised quality assurance standards.

See our comments on standard D.1.

E. The register

> E.1 The organisation focuses on promoting the health, safety and well-being of consumers, protecting the public and promoting confidence in its profession

We do not believe this standard adds anything to previous standards B.1, B.4 and C.6 but see our comments on those standards.

> E.2 The organisation maintains an up to date register, online, that is accessible and supports all those using it to make informed choices

To meet this requirement of allowing customers and potential customers to make informed choices, an organisation must publish contemporaneously:

1. The details of all allegations made against a registrant.
2. Details of any hearing held including the deliberations that lead to a case being dismissed or sanction imposed.
3. The sanctions imposed.
4. The outcome of any appeal.

These details must be linked to the entry for that registrant in the public register and such information to remain there for an appropriate period to be determined by the CHRE.

We strongly recommend that the standards require the organisation to publish annually:

1. The number of complaints received in the previous 12 months.
2. The number of these complaints that resulted in formal allegations being put.
3. The number of these allegations that resulted in disciplinary proceedings.
4. The number of cases dismissed and for what reason.
5. The numbers of each sanction that was imposed.
6. The numbers of cases that were appealed, with their outcome.

> E.4 The organisation checks at appropriate intervals that registrants continue to be fit to practise

We do not understand why there is a standard that requires an organisation to check at appropriate intervals that registrants continue to be fit to practice when there is no standard that requires organisations to check that registrants are fit to practice before being admitted to an Accredited Register.

Additionally, this standard is meaningless unless fitness to practice criteria are specified.

E.5 The organisation provides clear guidance to registrants and consumers

We recommend that it is a requirement of the standard that all guidance issued must be reviewed regularly and updated as required, particularly to ensure continued compliance with the law, consumer protection legislation[17] and guidance issued by the ASA.[18]

E.7 The organisation provides good advice and support for those providing evidence in disciplinary cases

We feel this is weak and recommend that this standard explicitly states that advice must be independent advice.

E.8 The organisation makes sound decisions, that are fair, transparent, consistent and explained clearly

If the public are to have any confidence in the independence of an organisation's complaints and disciplinary procedures, then such decisions and the process by which they are arrived at must be scrupulously fair and transparent.

We do not see how this could be the case where such cases are decided by fellow registrants or others closely connected or associated with that organisation.

We therefore recommend that the standards require a necessary degree of independence and separation between those charged with investigating and progressing complaints and disciplinary cases and the organisation's governing body and its registrants.

E.9 The organisation ensures appropriate action is taken when registrants are found to have failed to meet its standards, including referral to other agencies

In the interests of consistency across Accredited Register organisations and public confidence in those organisations, we recommend that the CHRE takes responsibility to define sanctions and appropriate disciplinary thresholds at which they must be invoked. We further recommend that the CHRE defines minimum periods for the operation of those sanctions.

We also recommend that organisations are mandated to ensure that all sanctions are clearly noted against the name of the registrant for the period of that sanction.

F. Complaints and concerns

F.2 The organisation's arrangements for handling complaints made to it are proportionate, fair, swift, focussed on restoring confidence and making amends, promoting learning and protecting service users

What is completely missing from these standards is the requirement for an organisation to publish their standards of practice, code of conduct and ethics against which their members will

[17] "The Consumer Protection from Unfair Trading Regulations 2008", n.d., http://www.legislation.gov.uk/ukdsi/2008/9780110811574/contents.

[18] "CopyAdvice - Copy Advice", n.d., http://copyadvice.co.uk/.

be held accountable and the complaints and disciplinary procedure that details the procedure that the organisation will follow in the event of a concern being raised about a member.

Without these, a customer or potential customer cannot know what to expect, what standards are to be expected and how a complaint will be dealt with.

We strongly recommend that it is a requirement of the standards for organisations admitted to the Accredited Register to publish these documents in a clear, helpful and easy to access format, preferably approved by Plain English Campaign[19] or at least conforming to their plain English principles.

G. Information

> G.1 The organisation provides clear, helpful, easy to access information. It ensures that information provided by the organisation and by its registrants helps consumers to make informed choices and exercise informed consent.

This requirement is key. As we have said above, unless customers and potential customers are given full and independent information about the evidence base and the possibly safety concerns for an alternative therapy, they cannot make informed choices and cannot exercise informed consent.

H. Premises, products and equipment

> H.1 The organisation provides clear guidance to registrants on any special requirements relating to the suitability of premises, products and equipment for the practise of their discipline which are essential to protect the health, safety and well-being of consumers

We recommend that the standards also mandate that registrants have appropriate liability insurance as a condition of admittance to an Accredited Register.

> H.2 The organisation requires its registrants, where relevant to their discipline, to use products and equipment that are approved as suitable and safe for use in health care

All medicines are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA). They also register some homeopathic products under various schemes.

There are currently 224 homeopathic products registered with the MHRA under its HR scheme, one registered under its NR scheme and a further 483 that have Product Licences of Right (PLR). These products are generally freely available to the public from a variety of outlets and this is not prohibited.

However, all other homeopathic products are categorised by the MHRA as 'unlicensed homeopathic medicines' following various EU Directives. As such, their manufacture, marketing, advertising, supply and usage are tightly regulated by the MHRA.

We understand that homeopaths regularly use such unlicensed homeopathic medicines and that they are even generally available to the public and homeopaths from a number of

[19] "Plain English Campaign Homepage", n.d., http://www.plainenglish.co.uk/.

manufacturers and suppliers. However, our understanding of the regulations is that only those medical professionals with Independent Prescribing Rights or Registered Pharmacists are legally entitled to supply such products to the public (with restrictions).

Because the majority of homeopaths are not medically qualified and do not fit into these two categories (ie they have no standing above any other member of the general public), we understand that they are not permitted to supply or even possess these unlicensed homeopathic medicines.

Additionally, Schedule 6 of the Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 2005[20] states that:

> OFFENCES, PENALTIES ETC
>
> Offences
>
> 1. Any person who, in breach of these Regulations, places a homoeopathic medicinal product on the market without holding a certificate of registration in respect of that product, or otherwise than in accordance with the terms of such a certificate, shall be guilty of an offence.
>
> 2. Any person who, in the course of a business carried on by him, sells, supplies, manufactures or assembles, or procures the sale, supply, manufacture or assembly of, a homoeopathic medicinal product, or who has in his possession a homoeopathic medicinal product, knowing or having reasonable cause to believe that the product was or is intended to be placed on the market contrary to paragraph 1 shall be guilty of an offence.

We understand from the above regulations that such supply is a breach of the regulations.

We therefore do not think it would be wise of the CHRE to be seen to endorse any register of homeopaths.

[20] "Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 2005", n.d., http://www.legislation.gov.uk/uksi/2005/2753/contents/made.

Overall recommendations

We have made recommendations throughout our response.

We also make the following overall recommendations and see these as essential to ensuring the CHRE fulfils its aims of promoting the health, safety and well-being of patients and other members of the public and to be a strong, independent voice for patients in the regulation of health professionals throughout the UK:

1. We strongly recommend that the CHRE do not allow onto their Accredited Register any organisation whose registrants provide alternative therapies that do not meet the basic requirements of having a robust evidence base or that does not have an assessment of safety that ensures that the public will be properly protected.

   We believe that to do so would be detrimental to:

   - the CHRE's reputation;
   - public confidence in the CHRE and its regulated professions;
   - public health and safety;
   - the reputation of other Accredited organisations.

2. We strongly recommend that the standards ensure that the public are given independent and unbiased information about the evidence base for treatments.
3. We strongly recommend that the standards ensure that the public are given independent and unbiased information about the risks associated with treatments.

We urge the CHRE to take note of all our recommendations.