

A proposal to establish a means to regulate the advertising of Complementary and Alternative Medicine as an alternative to the Advertising Standards Authority Ltd

A Draft Proposal and Practicality Review

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Circulation limited to attendees of the Complementary and Alternative Medicine organisations meetings.

Draft Proposal

A proposal to establish a means to regulate the advertising of Complementary and Alternative Medicine (CAM) as an alternative to the Advertising Standards Authority Ltd to work closely with the National Trading Standards Board (NTSB) or its delegate TSS under the control of the NTSB (to ensure consumer law enforcement), and to function as a self-regulatory agency compliance partner for the purposes of ensuring consumer protection.

1	The	ASA and CAM	1
	_	ablished Means	
		ntext	
4	Me	eting the requirements of a Compliance Partner	4
	4.1	Essential qualities/systems for a Compliance Partner	4
	4.2	Desirable qualities/Systems	6
5	Evid	dence of unity by CAM disciplines	7
6	Adr	Administration and Financial Considerations	
7	Risk	ks	8
Q	Eur	ther requirements	Q

1 The ASA and CAM

The relationship between the CAM professions and the ASA has reached what has been described by the Alliance for Natural Health as "an all-time low", particularly since the extension of the ASA's remit to make 'rulings' ('adjudications') upon online marketing and media material;

CAM Practitioners and institutions are making their views known. Campaigns are already in progress, including those by Freedom4Health and by the holistic hormone health specialist Dr Alyssa Burns-Hill.

The basis of the dispute is the allegation that the ASA adjudication process is flawed and unfair in that it fails to properly take account of representations made and evidence provided by CAM Practitioners or to fully comply with Human Rights and the principles of Natural Justice.

In an article published in the January 2014 edition of CAM Magazine, Dr Alyssa Burns-Hill is quoted as saying that the ASA is "overstepping the mark in terms of their remit" and that it has an "inability to stand back and look at their own procedures and how out of control they are".

"Freedom4Health" is also quoted, as follows:

"The UK Advertising Standards Authority has shown bias and disregard for evidence when investigating the advertising of complementary, holistic and integrative medicine. It acts as prosecutor, judge and jury in one....and publishes highly questionable 'adjudications'..."

H:MC21 ("Homeopathy: Medicine for the 21st Century") is a charity established, amongst other things, to inform the public of the facts about homeopathy and its historical and scientific relationship to orthodox medicine. It aims to do this through research, publication and campaigning. An extract taken from a press release issued by H:MC21 and posted on its website, reads as follows:

"The adjudication is not about consumers; it is about suppressing the charity's ability to inform the public of the demonstrated facts that set out a clear argument for homeopathy as a legitimate, cost effective and safe alternative to conventional medicine."

The jurisdiction and power of the ASA should not be underestimated. On its website, the ASA has stated that the professional and brand damage sustained by an advertiser after having an advertisement banned by the ASA can be devastating.'

2 Fstablished Means

On its website and in communication with CAM practitioners the ASA makes repeated mention of its status as an "established means". Paragraphs 3.5 to 3.8 at pages 9 & 10 of The Competition and Markets Authority (CMA) guidance document CMA58 (17.08.16) describe the current regulatory process in relation to the operation of the CMA, as follows:

"UK and EU consumer legislation encourages, and at certain points requires, cooperation between bodies exercising consumer functions to ensure the most appropriate mechanism is used to achieve compliance, Including potential alternatives to enforcement action. Under the Consumer Protection from Unfair Trading Regulations 2008, the CMA is required to 'have regard to the desirability of encouraging control of unfair commercial practices by such established means as it considers appropriate having regard to all circumstances of the particular case'. The Business Protection from Misleading Marketing Regulations 2008 contain similar provisions.

These provisions are intended to encourage the use of arrangements other than direct enforcement, where appropriate, as a means of controlling unfair commercial practices

and misleading marketing activities. Bodies with other powers, such as the Advertising Standards Authority (ASA), which is the UK's independent regulator of advertising across all media, are regarded as suitable in principle to act as constituting 'established means' in the sense referred to above, and thus as compliance partners for the purposes of ensuring consumer protection.

The CMA seeks to refer a matter to the compliance partner best placed to resolve the problem. When making this assessment, the CMA satisfies itself that the chosen partner has an effective way of bringing about the control of unfair commercial practices. The primary aim is to gain compliance in the most cost effective and least burdensome way that maximises the reach of consumer law. In deciding how to proceed, the CMA takes account of all relevant circumstances, and will not rely on established means, where it considers this to be inappropriate."

3 Context

This document investigates the practicalities of the proposal in relation to how existing compliance partnership requirements may be addressed as well as considering funding and engagement structures. It should be viewed as a second-stage discussion document.

The proposal recognises that the General Regulatory Council for Complementary Therapies (GRCCT) Advertising Certification process is the only vehicle which, when appropriately supported, can currently meet the requirements of a Compliance Partner. It is anticipated that after a period of successful operation (between 5 years and 7 years) Advertising Certification will be self-funding and in possession of sufficient supporting resources to enable uncoupling from GRCCT and establishment as an independent body.

4 Meeting the requirements of a Compliance Partner

The CMA Consumer protection: enforcement guidance published 17 August 2016 (CMA58) describes the UK's consumer protection regime since it was reformed following consultation in 2012. The outcomes of the consultation altered both the institutional structure and the roles and responsibilities of consumer protection bodies.

The reforms confirmed that it was the CMA's mission to focus on the working of markets and accordingly gave key compliance partners of the CMA a national lead in certain other areas which had previously fallen to the Office of Fair Trading (OFT). In particular they gave the Trading Standards Service (TSS) a leadership role in relation to the bulk of UK consumer enforcement.

For clarity, this proposal uses Office of Fair Trading Response to consultation on Compliance partnerships (OFT 1043resp July 2009) together with guidance issued by the CMA (CMA7, March 2014, paragraphs 4.34 & 4.35 at page 20 which, although withdrawn and replaced by CMA58, the CMA confirms continues to apply) as the primary source documents for required and desirable qualities expected in Compliance Partners

It is apparent that the majority of both essential and desirable qualities/systems expected in a Compliance Partner are integral to the establishment and successful operation of an independent regulator.

4.1 Essential qualities/systems for a Compliance Partner

1. Adequate Resources

GRCCT has robust decade-long history of administering a national voluntary regulatory process extending to some 18500 individuals in 22 different CAM disciplines. Resource reviews are part of the inhouse annual review process.

- 2. Law abiding in operation
 - a. The establishment and operation of a national voluntary regulatory body is by nature law abiding. GRCCT has operated for ten years without legal challenge to its operation, procedures or rulings.
 - b. The requirement for Registrants to act lawfully is enshrined in section 1.1 of the GRCCT Code of Conduct by which registrants are bound.
- 3. Recognition within its community
 - a. Out of the estimated 41000 CAM practitioners in 31 defined disciplines practising in the UK, GRCCT currently regulates 18500 in 22 disciplines. In percentage terms, the GRCCT can demonstrate engagement with 45% of all CAM practitioners in 70% of the defined CAM disciplines.
 - b. With the involvement of Acupuncture, Herbal Medicine, Homeopathy and Naturopathy the evidenced percentage would increase to 61% of practitioners in 83% of defined disciplines.

c. The involvement of other disciplines such as TCM and Ayurvedic Medicine would increase the evidenced recognition further but the current disparate nature of these disciplines is a challenge for the level of engagement and time schedule required in this proposal. It may be possible to begin discussions with elements within these disciplines and report such as part of the submission.

4. Properly incentivised to act

- a. The responsibility of a regulator is to the public. It serves to protect the consumer. The structure, processes and procedures of GRCCT are all directed to this primary responsibility.
- b. GRCCT is a non-profit body in which funding is decoupled from those providing profession knowledge to the Council by several levels.
- c. GRCCT is funded only by its registrant services. It does not accept sponsorship, contributory payments, donations, payments in kind, or any form of funding outside designated by its regulatory remit. In this manner conflict of interest or external influence are obviated.
- 5. Systems to place requirements on its community
 - a. The engagement with the regulator by profession associations and profession councils provides a top-down route for placement of requirements onto individual sectors or the whole community
 - b. Direct communication with each individual registrant provides a robust audit trail for placement of requirement.
- 6. Systems to enforce those requirements within its community
 - a. GRCCT works proactively with profession associations, lead bodies and profession councils to oversee the incorporation of regulatory requirements into applicable Codes of Conduct and membership requirements. The profession membership requirements are the most effective enforcement tool.
 - b. As a voluntary regulator GRCCT is akin to the ASA in its limited powers however unlike ASA, GRCCT's engagement with the profession associations and individual practitioners means that for those who breach the requirements there are a range of proportionate sanctions available. These include, but are not limited to:
 - i. communication with other profession bodies so that access to profession services and insurance is restricted.
 - ii. notification of ruling on profession body sites as well as (if applicable) the publicly searchable area of the GRCCT National Register.
 - iii. Practitioners holding GRCCT registration are seen to meet NHS Patient Safety Criteria. In the case of non-compliant practitioners this may be revoked.
 - iv. Referral to enforcement bodies such as Trading Standards or the Police.
- 7. An appropriate degree of independence in governance
 - a. The Line of Separation in the GRCCT is identical in position to that of most statutory regulatory bodies. In the same manner as orthodox medicine regulatory bodies such as General Medical Council and the Nursing and Midwifery Council, professions have knowledge presentation at the level of the Federal Regulatory Council (the 'top table') but the profession representation is outnumbered by lay representation.

- b. In accordance with recommendations of the <u>Better Regulation Executive</u> there is also a lay Board of Trustees with power of oversight. Whilst the Board of Trustees may not overturn a decision of the Council they may uphold points of order and ask the Council to reconsider a decision.
- 8. Appropriate degree of objectivity in governance
 In a similarity with the response to '7a' above, GRCCT can evidence an appropriate Line of
 Separation and a lay-majority Council. In combination with a lay Board of Trustees this
 provides robust evidence of objectivity in governance.
- 9. Regard for principles of better regulation and the Human Rights Act
 - a. The five principles identified by the Better Regulation Task Force in 1997 (Accountability, Consistency, Proportionality, Targeting, Transparency) are integral to the operations processes of GRCCT. Mapping of operations protocols against the Principals, the relevant sections of the Legislative and Regulatory Reform Act 2006, and the polices of the Better Regulation Executive form part of the annual operations review.
 - b. In a similar manner to the principles of Better Regulation, regard to the Human Rights Act is enshrined in GRCCT administrative and operational protocols.
- 10. Adequate controls in place for the safeguarding of confidential information
 - a. Compliance with the Data Protection Act 1998 is integral to the daily operation of the regulatory process.
 - b. All staff receive in-house training in accordance with the <u>ICO Training checklist for small and medium sized organisations</u> at induction as a part of the Staff Continuing Professional Development protocol.
- 11. Reporting to the oversight body

The administration of the GRCCT is overseen by the Federal Regulatory Council. The Council receives a set of detailed operations reports at their quarterly meetings. These reports are appropriate to any external requirement.

4.2 Desirable qualities/Systems

- 12. Systems for providing information/communication within markets
 - a. GRCCT operates a Secure Access Platform for direct communication to the 22 regulated disciplines. This is monitored and provides robust, time-evidenced communication data.
 - b. Engaged profession bodies disseminate information as part of their route of knowledge undertakings.
- 13. A public facing element that may incorporate a complaint handling facility
 - a. The Advertising Certification area of the GRCCT website provides a public-facing element with discipline-specific information on legal and profession requirements for advertising.

b. The current complaint procedure simply defines how a complaint should be structured and delivered. As a compliance partner, it is anticipated that a higher volume of complaints will need to be addressed. An online system with automated acknowledgement and a robust audit trail for communication and action markers is required. The software has been commissioned and the facility is anticipated to be in place by the beginning of September 2017.

14. Systems for staying abreast of developments in the law

- a. GRCCT has a documented history of involvement with an extensive range of consultative processes including NICE, NOS, NMC, PSA and various Committees.
- b. Representatives from GRCCT are members of nine All Party Parliamentary Groups.
- c. A parliamentary information subscription service provides a weekly report on House of Commons and House of Lords activity including: Committee Publications, Research Briefings, Westminster Hall Debates and Bills in Transit.
- d. A second information provider company supplies a key-point Hansard report together with monthly reports on:
 - i. Commons Select Committees for: Education, Health, Regulatory Reform, and the Statutory Instruments Committee.
 - ii. Lords Select Committees for: Delegated Powers and Regulatory Reform, Science & Technology Select Committee, NHS Sustainability Committee.

5 Evidence of unity by CAM disciplines

1. Disciplines impacted by ASA action

It is apparent that almost all CAM disciplines are receiving communication from ASA to a greater or lesser degree. The existing numbers for registrations are impressive (see 1.1.3a) however the numbers of engaged disciplines outside the regulatory process (evidencing sector unity) is considered to be a vital component in the success of the proposal. As such, engagement was as many disciplines as possible in advance of submitting the proposal is essential.

- 2. Routes for engagement
 - a. Direct engagement by adoption of federal regulation

 Establishing a GRCCT National Register Entry Category for each discipline would be the most robust method of evidencing engagement. A number of factors including time-constraints and disparate nature of some disciplines preclude this as an option in advance of action under this proposal.
 - b. Engagement via the Advertising Certification process

 The option exists to evidence disciplines engagement via the Advertising Certification process. This will require a Letter of Undertaking from each profession association or discipline representation. It will need to include a commitment to provide profession expertise appropriate to the ongoing requirements of the GRCCT Advertising Certification Panel, (including expert witness testimony) and Certification of the profession association website.

6 Administration and Financial Considerations

1. Staffing

- a. The current administration team of six staff are all multi-role trained so may be work-load tasked as needed between administration of the National Register and administration of the Advertising Certification process.
- b. Six additional staff are trained on our systems and available at short notice on contract from a national recruitment agency.

2. Administrative resources

The GRCCT are experienced in addressing the additional demands on resources when large numbers of practitioners apply for admission over a short period of time. This occurs whenever a new Register Category is opened. Provision is in place for 'bulge' requirements such as additional phone lines and automated response services.

3. Financial Considerations

- a. Profession associations seeking to engage with the Advertising Certification process without regulatory engagement will be charged an annual Certification fee for their website on a per-capita basis and calculated at a rate of between £5 and £8 dependant on size and risk considerations.
- b. The fees for Advertising Certification charged to members of engaged bodies will be reduced from £225-£265 to a flat rate of £145 to facilitate access and encourage uptake in newly engaged disciplines.
- c. The initial submission preparation, submission and negotiation for this proposal will be financed from the exiting GRCCT operations budget.
- d. The Advertising Certification Process is non-profit and self-funding. Pump-priming funds to the value of £250,000 will be made available at inception from the GRCCT Disciplinary Reserve Fund to cover costs incurred during the first 30 months of operation. This availability will be in the form of £180,000 available during the first 18 months of operation and a further £70,000 will be made available for months 19 to 30 if required.

7 Risks

A broad-focus risk assessment is currently being undertaken. Early indications (based on this draft) highlight several high impact factors rating medium risk but no high risk, high impact factors.

8 Further requirements

To be effective, the final proposal to be submitted to the NTSB will need to include:

- a. A Dossier of Evidence (as discussed at the last meeting)
- b. List of supporting organisations with status indicators
