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AHMTCM Consultation Team
Department of Health
Room 2N09
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16th November 2009

Dear Sir or Madam

Re: A joint consultation on the Report to Ministers from the DH Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK

The Royal College of Physicians is grateful for the opportunity to respond to the above. We would like to make the following comments.

Question 1
What evidence is there of harm to the public currently as a result of the activities of acupuncturists, herbalists and traditional Chinese medical practitioners? What is its likelihood and severity?

There are significant risks, particularly related to the use of herbs, which are well summarised in Annex B of the consultation document.

Question 2
Would this harm be lessened by statutory regulation? If so, how?

In one sense, the potential for harm should be already mitigated by issues relating to any product or service covered by the legislation relating to consumer protection. Extending statutory regulation as relates to conventional practitioners of medicine to these new areas would only reduce risk if regulation was performed in such a way as to guarantee and make enforceable standards of training, practice and ethics of practitioners. Also, only if this would bring along with it requirements for clinical governance, continuing professional development etc. This approach would be completely inappropriate for those 'disciplines' of complementary therapy whose therapies are neither of proven benefit nor appropriately tested. Excluding these from the umbrella of respectability that regulation as a medical procedure confers would minimise the potential for harm. Conversely, extending the imprimatur of statutory regulation analogous to that applied to medical, nursing, dentistry, and physiotherapy, to practitioners whose therapies are neither of proven benefit nor appropriately tested has the potential to increase the possibility of harm.

Question 3
What do you envisage would be the benefits to the public, to practitioners, and to businesses, associated with introducing statutory regulation?

The public would benefit from guaranteed, high and transparent standards of training, practice, ethics and clinical governance in respect of therapies that are of proven efficacy and/or benefit. Conversely, exclusion of 'rogue practitioners' and practitioners of therapies of proven benefit from the

imprimatur/recognition of a statutory regulation process would alert the public to the potential for harm implicit in seeking advice from such practitioners. Such harm could derive either from the therapies administered or from opportunities for conventional medicine deferred.

Question 4
What do you envisage would be the regulatory burden and financial costs, to the public, to practitioners, and to businesses, associated with introducing statutory regulation? Are these costs justified by the benefits and are they proportionate to the risks? If so, in what way?

In view of the wide use of these therapies and the presence of associated risks, enhanced regulation justifies the costs. There are however already means of regulation notably the regulation of practitioners of Western Medical Acupuncture performed by members of the British Medical Acupuncture Society (BMAS). These practitioners are already regulated health care professionals meeting the requirements of their regulators and professional bodies.

In respect of businesses, it is worth commenting however that a combination of lack of statutory regulation of herbalists and traditional Chinese medical practitioners and European Directive 2001/83/EC might combine to have a serious negative impact. Significant numbers of 'finished' complex products currently in use would become unavailable. The market for these would not vanish but would move, mostly to the Internet. There would be no quality control on products sold in this way. The use of internet trading however is used widely and not limited to these products.

Question 5
If herbal and TCM practitioners are subject to statutory regulation, should the right to prepare and commission unlicensed herbal medicines be restricted to statutorily regulated practitioners?

Yes.

Question 6
If herbal and TCM practitioners are *not* statutorily regulated, how (if at all) should unlicensed herbal medicines prepared or commissioned by these practitioners be regulated?

Unlicensed herbal medications should be subject to a rigorous assessment in terms of efficacy and safety. Those that are effective should be licenced. The public should be protected from those that are not by consumer protection legislation and not by employing/extending inappropriately existing statutory regulation designed to be applied to medicines of proven effectiveness.

Question 7
What would be the effect on the public, practitioners and businesses if, in order to comply with the requirements of European medicines legislation, practitioners were unable to supply manufactured unlicensed herbal medicines commissioned from a third party, after 2011?

There would be negative impacts for both businesses manufacturing these products and herbal and traditional Chinese medical practitioners. By contrast, this would be balanced by improved protection of the public from potential adverse effects of unlicensed medications.

Question 8

How might the risk of harm to the public be reduced other than by statutory professional self-regulation? For example, by voluntary self-regulation underpinned by consumer protection legislation and by greater public awareness, by accreditation of voluntary registration bodies, or by a statutory or voluntary licensing regime?

A statutory licensing regime with a properly defined and regulated accredited qualification.

Question 9
What would you estimate would be the regulatory burden and financial costs, to the public, to practitioners, and to businesses, for the alternatives to statutory regulation suggested at Question 8?

Significantly less than statutory regulation.

Question 10
What would you envisage would be the benefits to the public, to practitioners, and to businesses, for the alternatives to statutory regulation outlined at Question 8?

Financial benefit. Also the public would be protected from the use of alternative therapies of no benefit which might be made respectable by the dignity of statutory regulation of medical practice.

Question 11
If you feel that not all three practitioner groups justify statutory regulation, which group(s) does/do not and please give your reasons why/why not?

Acupuncture, using definitions similar to those advocated by the British Medical Acupuncture Society (where there is proof of efficacy) should be considered appropriate for statutory regulation as a medical procedure. Herbal and traditional Chinese medicines which are largely or completely of unproven benefit should be regulated in terms of consumer protection.

Question 12
Would it be helpful to the public for these practitioners to be regulated in a way which differentiates them from the regulatory regime for mainstream professions publicly perceived as having an evidence base of clinical effectiveness? If so, why? If not, why not?

Yes - as the vast majority of herbal and traditional Chinese medication is not based on scientific evidence of efficacy. Regulation (except for acupuncture) by regimes similar to those applied to medicine nursing midwifery etc runs the risk of leading the public to believe that these complementary approaches have a similar efficacy.

Herbal and Traditional Chinese medicine would need to progress to a stage at which practice was required to be based on the processes of evidence based medicine as originally defined by Sackett[1]. There would need to be the expectation that the sector would do all it can to develop and improve the evidence available. Considerable further work would be required to have been completed including working closely with the MHRA on the continuing process of herbal safety and quality as well as identifying and managing adverse reactions to herbals. Practitioners would have to satisfy educational qualifications equivalent to a 3 to 4 year, full-time university course which involves education in pharmacology and conventional medicine.

(The latter is already happening under the system of voluntary regulation, with courses in or allied to universities and associated with an independent accreditation process).

All practitioners should have a good command of English, as would be expected of any clinician practising in the UK and would need to participate in a process of continuing professional development that involves adherence to the principles of evidence-based medicine.

Question 13
Given the Government's commitment to reducing the overall burden of unnecessary statutory regulation, can you suggest which areas of healthcare practice present sufficiently low risk so that they could be regulated in a different, less burdensome way or de-regulated, if a decision is made to statutorily regulate acupuncturists, herbalists and traditional Chinese medicine practitioners ?

Regulation of herbalists and traditional Chinese practitioners in terms of consumer protection law here would be less burdensome.

Question 14
If there were to be statutory regulation, should the Health Professions Council (HPC) regulate all three professions? If not, which one(s) should the HPC not regulate?

No. If there were to be statutory regulation via HPC it should apply to Acupuncture only.

Question 15
If there were to be statutory regulation, should the Health Professions Council or the General Pharmaceutical Council/ Pharmaceutical Society of Northern Ireland regulate herbal medicine and traditional Chinese medicine practitioners?

We do not agree that there should be but if so, regulation via the General Pharmaceutical Council would be more appropriate.

Question 16
If neither, who should and why?

See 15.

Question 17
a) Should acupuncture be subject to a different form of regulation from that for herbalism and traditional Chinese medicine? If so, what?

Yes. See above.

b) Can acupuncture be adequately regulated through local means, for example through Health and Safety legislation, Trading Standards legislation and Local Authority licensing?

It could be regulated in that way, but in respect of Western Medical Acupuncture we have argued for its regulation through the Health Professional Council.

Question 18
a) Should the titles "acupuncturist", "herbalist" and "[traditional] chinese medicine practitioner" be protected?

Not all.

b) If your answer is "No", which ones do you consider should not be legally protected?

"herbalist" and "[traditional] chinese medicine practitioner"

Question 19
Should a new model of regulation be tested where it is the *functions* of acupuncture, herbal medicine and TCM that are protected, rather than the *titles* of acupuncturist, herbalist or Chinese medicine practitioner?

Such a model of regulation is likely to be problematic. It would create difficult precedents, potential anomalies and contradictions, for little benefit. Moreover, the practicalities of developing competencies and assessing their attainment by practitioners, which would be necessary, should only be attempted in areas where efficacy and benefit have been shown (e.g. acupuncture). Where this has not been proven the title conferred on is irrelevant. Regulating the title used again confers respectability and credibility on practices of unproven benefit.

Question 20
If statutory professional self-regulation is progressed, with a model of protection of title, do you agree with the proposals for "grandparenting" set out in the Pittilo report?

No.

Question 21
In the event of a decision that statutory or voluntary regulation is needed, do you agree that all practitioners should be able to achieve an English language IELTS score of 6.5 or above in order to register in the UK?

Yes.

Question 22
Could practitioners demonstrate compliance with regulatory requirements and communicate effectively with regulators, the public and other healthcare professionals if they do not achieve the standard of English language competence normally required for UK registration? What additional costs would occur for both practitioners and regulatory authorities in this case?

It would seem that by definition practitioners would be unable to communicate effectively with regulators, the public and other healthcare professionals if their English was poor, unless translation services were available.

Question 23
What would the impact be on the public, practitioners and businesses (financial and regulatory burden) if practitioners unable to achieve an English language IELTS score of 6.5 or above are unable to register in the UK?

The impact would be small if it applied only to 'grandparented' practitioners.

Question 24
Are there any other matters you wish to draw to our attention?

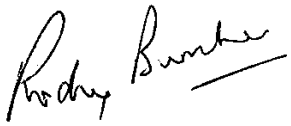
We have concerns about 'Dual/distributed regulation' (p34-35 of the Consultation document), although no questions are asked about this. It presents three options: Dual registration; Registration with only the primary regulator with annotation; Regulation with only the primary regulator without annotation. The first and third options, as the document points out, are problematic. In fact all of these options are likely to generate difficult precedents, anomalies and contradictions. Significant numbers of doctors and other health professionals use methods which are, or may become, the subject of statutory regulation when practised by 'stand-alone' therapists. Examples include the use, by doctors, of spinal manipulation (similar to methods used by osteopaths and chiropractors), psychotherapy, homeopathy, dietary and nutritional therapies and indeed acupuncture, among others. Making judgements about which of these therapies, under which circumstances, would require annotation by the primary regulator would be difficult. This is not to deny that this may be an issue of concern, but it should be dealt with by the primary regulator (the GMC in the case of doctors).

In summary

Overall, we recognise that regulation of practitioners and therapists is a major power for good. The arrangements within medicine, nursing, midwifery, dentistry, physiotherapy etc are not only beneficial to patients but to the practitioners themselves. However such 'medical'-type regulation is conferred by society with the express recognition that the therapies offered are beneficial, which means – although not necessarily so defined at the time the regulatory authorities were set up – that the therapies are in large part based on demonstrable evidence of efficacy, in addition to custom and practice. Thus, this form of medical regulation carries with it a societal imprimatur of efficacy. In our judgement, only certain areas of acupuncture (referred to as Western Medical Acupuncture) have reached this threshold and been recommended by NICE. We do not believe that herbalism, Traditional Chinese Medicine or indeed any other forms of alternative medicine attain this threshold. Alternative forms to protect the public e.g. through consumer protection laws, and by the licensing or withdrawal of unlicensed herbal preparations, are more appropriate.

I trust these comments will be of use.

Yours faithfully



Dr Rodney Burnham
Registrar

Reference

[1] ‘‘*Evidence-based medicine is not restricted to randomised trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions.…If no randomised trial has been carried out for our patient’s predicament, we follow the trail to the next best external evidence and work from there.*’’

Sackett DL, Rosenberg WMC, Muir Gray JA, et al. Evidence based medicine: What it is and what it isn’t. *BMJ* 1996;312:71–72.