Interview with Michael McIntyre of the European Herbal and Traditional Medicine Practitioners Association.

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The matter of statutory regulation of herbal medicine and acupuncture practitioners has been on the political agenda since 2000 when the House of Lords’ Select Committee on Science and Technology called for the statutory regulation of this sector. In 2001 the Government responded to the Select Committee saying that it agreed that statutory regulation should go ahead. Since that time the Department of Health has launched three working groups to consider how best this can be achieved, the last of these reported in 2008. All have echoed the Select Committee’s finding that statutory regulation should be implemented as soon as possible.

The reason why statutory regulation is so important is that it provides protection for the public who wish to use herbal medicine from fraudulent or failing practitioners. Research carried out by Ipsos Mori for the MHRA published in 2009 found that in the previous two years, 5% of adults in Great Britain (one in twenty) had used herbal medicines obtained from a practitioner of traditional Chinese medicine and 8% (one in twelve) had used herbal medicines obtained from a Western or other traditional practitioner. In total 26% had used herbal medicines in the previous two years and 35% at some time in the past, whether bought over the counter or obtained from a practitioner. Around 12.5 million people used herbal medicines 2006 – 2008, and more than six million adults in Great Britain had consulted a herbal practitioner. Asian (17%) and BME groups (15%) were more likely than White groups (7%) to have consulted a practitioner. Given the popularity of these treatments it is evidently important that the public can select trained and competent practitioners. At present, there is no sure way that such practitioners can be identified.

A second reason why statutory regulation of herbal medicine and acupuncture practitioners is vital is that without it, after April 2011, many herbal medicines prescribed by these practitioners will no longer be available leading to a significant loss of consumer choice. The reason for this is that in April 2011, the European Directive on Traditional Herbal Medicinal Products will be fully implemented and this will see the end of Section 12 (2) of the 1968 Medicines Act which allows the supply of herbal medicines to herbal practitioners by manufacturers for prescription to individual patients. From this time, the only herbal medicines that practitioners can prescribe are those they make up on their own premises. This situation can only be avoided if herbal practitioners are statutorily regulated. This will permit practitioners to be recognised as ‘authorised health professionals’ under the main European Medicines Directive (2001/83/EC) and thus be able to commission medicines from manufacturers and suppliers for their patients under Article 5.1 of the Medicines Directive. The clock is ticking on this which is another reason statutory regulation must be granted to this sector without delay.

A third reason that statutory regulation is important is that it brings herbal practitioners and acupuncturists into the general framework of healthcare professionals. This will enable doctors to refer patients to practitioners within this
sector and patients to feel comfortable about discussing their acupuncture and herbal treatments with doctors and other health professionals. In addition, health insurance schemes can include acupuncture and herbal treatments in the treatments that they cover whilst universities can be assured that the courses they run in herbal medicine, traditional Chinese medicine and Ayurveda are to qualify graduates for professions recognised and regulated by the state.

**Question: How widely is the Department of Health consulting on this issue?**

The Department of Health is consulting across the UK but there are problems with its consultation. Its questions are so complex and difficult few people can answer them. The first asks: ‘**What is the evidence of harm . . . What is its likelihood and severity?**’ Others ask for estimates of costs, the “regulatory burden” and alternatives to statutory regulation. One even suggests there is no evidence base for herbal medicine: a claim that is patently untrue and absurd.

Herbalist Michael McIntyre, Stakeholder Chair on the Department of Health’s Committee that recently recommended statutory regulation for herbalists and acupuncturists and Chairman of the European Herbal and Traditional Medicine Practitioners’ Association, says:

> “Patients are telling herbalists around the country that they have tried to respond to the consultation questionnaire – but are unable to do so. You would need to be an expert in medicines law or regulation to answer most of the questions.

> “This is the second Government consultation on regulation of herbal medicine. The first, published in 2005, received an overwhelming response in favour. Perhaps this time, they want to make it more difficult for ordinary patients to get a say.”

The Department of Health consultation questionnaire can be found at: [http://www.info.doh.gov.uk/questionnaire/ahmtcm_consultation.nsf](http://www.info.doh.gov.uk/questionnaire/ahmtcm_consultation.nsf)

**Question: Do you think there are any feasible alternatives to statutory regulation?**

The DH consultation document suggests other options than statutory regulation, none of which have any merit. These are:

1. The abolition of the Section of the 1968 Medicines Act (Section 12(1)) under which herbalists are permitted to practise. This would mean the end of all herbal practice in the UK and, given the popularity of herbal treatment, is clearly a ridiculous suggestion.

2. Voluntary regulation. This is how things are at present with a number of professional associations offering voluntary regulation and practitioners free to practise without belonging to any well run group. This leaves the public unable to distinguish between the well trained and competent and those who are fraudulent and failing. In addition, as explained above, after 2011, without statutory regulation, there will be a significant loss of herbal medicines and it is clear that access to a full range of herbal medicines can only be preserved if herbal/traditional medicine practitioners are statutorily regulated. For this reason, voluntary regulation is not an acceptable option.

3. A third possibility suggested by the Consultation Document is that of statutory licensing which will crucially confer no special legal rights when it comes to medicines law (see above) and will relegate herbal/traditional medicine and
traditional acupuncture practitioners to a second-rate category, using a similar licensing scheme to that currently employed to regulate bouncers, bodyguards and wheel clammers!

**It is clear that there are no feasible alternatives to statutory regulation.**

**Question: Is it likely that the government will not decide in favour of statutory regulation?**
If you had asked us that question some eighteen months ago we would have answered “No - the Government is committed to statutory regulation of this sector”. In 2006 the Department of Health website said:

“The Government is committed to the statutory regulation of herbal medicine, acupuncture and traditional Chinese medicine practitioners. We are in the process of setting up a Joint Working Group. We hope to have the Working Group set up and the first meeting arranged around June 2006 and to move gradually towards statutory regulation, probably in 2008/9.”

However, it now seems that the Government is dragging its feet over this issue. One of the problems is that this regulatory question has been overseen by at least a dozen ministers over the last decade and this has meant lack of continuity and organisational amnesia by the Department of Health as Government policy on regulation has chopped and changed. The Government has singularly failed to deliver on its undertaking to provide statutory regulation for this sector and the public stand to lose access to many herbal medicines as a consequence.

**Question: How will the failure to regulate disrupt the provision of herbal medicines?**
This is explained in detail in our answer to the first question above.

**Question: The Health Professions Council may become the new regulator of herbal practitioners. Would you support this decision?**
We support the health Professionals Council (HPC) as regulator of acupuncture, herbal/traditional medicine and traditional Chinese medicine. The HPC already regulates a diverse range of professions e.g. paramedics and art therapists and is therefore the best suited body to regulate herbalists, acupuncturists and TCM practitioners. The Department of Health Steering Group on the regulation of this sector under the chairmanship of Professor Michael Pittilo (published in 2008) reviewed the question of which regulator would be most appropriate. Regarding the HPC, it said:

“The Steering Group recognises that the creation of several statutory regulatory bodies to accommodate the wide range of professionals that exist is neither practical nor consistent with the recommendations within the White Paper, Trust, Assurance and Safety – the Regulation of Health Professionals in the 21st Century and Government policy to reduce the numbers of regulatory bodies. We are mindful that costs are reduced as a statutory regulatory body increases in size... The Steering Group takes the view that effective, safe and cost-effective statutory regulation has been demonstrated by the multi-professional Health Professions Council (HPC) and is convinced that this could be extended to cover practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional-medicine systems practised within the UK...
The Steering Group has every confidence in the ability of the HPC to statutorily regulate practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems effectively and efficiently and thus to protect the public from poor practice.”

Question: What has the support from parliamentarians been like on this issue?
Patients and the public are now writing in very large numbers to their MPs telling them that they want statutory regulation of herbal/traditional medicine and traditional Chinese medicine practitioners and acupuncturists and many MPs are taking up this matter with the Government. In particular, both the Conservative Health Spokesmen, Earl Howe for the Conservatives and Norman Lamb for the Liberal Democrats, have tabled Parliamentary questions on this subject and continue to take a very active interest in the process.