

Answers to questions from the American Herbal Guild

From Michael McIntyre, Chair of the European Herbal and Traditional Practitioners Association (EHTPA) 10/01/2010

1. Can you please give us a synopsis of the way UK herbalists were regulated prior to this latest political challenge?

The basis of the legal system in the UK is common law: in contrast to most of the rest of Europe which is based on Napoleonic Code, UK common law has it that unless an action is said to be illegal, it is not against the law. This is important because it means that, providing a patient is willing, it is legal for them to be treated by someone else whether or not that person is a registered medical doctor. This remains the case today but medicines law is now determined by the European Union and this is one reason why herbalists are now seeking statutory regulation.

In April 2011, the new European Traditional Herbal Medicinal Products Directive (THMPD) becomes fully operational and this will effectively replace one of the two pieces of legislation under which herbalists practise in the UK. This is Section 12(2) of the 1968 Medicines Act which currently allows finished herbal products and prescriptions to be supplied to patients by a third-party herbal manufacturer or supplier. From April 2011 such supplies would require a traditional medicines registration under the THMPD and while this may be appropriate for over-the-counter herbal products, it certainly is not viable for small quantities of herbal products that are used for specific patients. It takes months or years to acquire a THMPD licence and costs thousands of dollars so this route is closed to practitioners using herbal medicines tailored to treat individual patients. Thus full implementation of the new THMPD will see the end of the right of practitioners to access finished medicines from manufacturers and herbal suppliers for prescription to individual patients. This includes all finished products such as medicinal herbal pills, tablets, capsules, dried herb mixtures and medicinal herbal ointments made up for individual patients by third-party suppliers. Also under threat are third-party herbal prescription services that supply individualised herbal prescriptions (including those comprising tinctures and dried herbs) to named patients at the practitioner's request. Over the past 40 years this mode of supply has become an essential part of herbal practice in the UK and many practitioners are totally reliant on such services. All that will remain will be herbal medicines prepared by practitioners from their own premises under another still existing statute – Section 12(1) of the 1968 Medicines Act.

Section 12(1) allows a practitioner (the word herbalist does not appear in the legislation) to prescribe a herbal medicine to a patient provided the practitioner has seen the patient in person and supplies the medicine from premises capable of being locked from the public (i.e. not a market stall) of which he or she is the occupier. This essential part of the 1968 Medicines Act is still viable in 2010 and beyond because, the products supplied are made up on the practitioners own premises and are not “industrially produced”. The phrase “industrially produced” is used in the main EU Medicines Directive (2001/83/EC) to define medicines that must have a full market authorisation (i.e. licence). Because the prescriptions herbalists make on their own premises are not industrially produced, they do not need a medicines licence.

Nevertheless the loss of third-party supply is a huge blow to herbalists and their patients. Without statutory regulation, from this time onwards, many patients will be unable to obtain their usual medicines. The loss of this facility will put many practitioners and several of their suppliers out of business. Statutory regulation solves the problem because it enables

herbalists to be recognised as “authorised health professionals” under the main EU Medicines Directive and as authorised health professionals, herbalists will be able to commission herbal products and finished prescriptions from third-party suppliers.

2. Were consumers pretty satisfied with the care they received from herbalists?

Herbal medicine is extraordinarily popular. Recent research by Ipsos MORI for the Medicines and Healthcare products Regulatory Agency (MHRA) has found that millions of people in the UK use herbal medicines and that more than a quarter of the population had bought herbal medicines over-the-counter in the previous two years with one in twelve consulting a practitioner of Western herbal medicine and about one in twenty consulting a practitioner of traditional Chinese Medicine. It also noted that 77% of adults agree it is important that herbal medicines are regulated, with this figure rising to 87% among regular users of herbal medicines (defined as those who have used a herbal medicine within the last 2 years).¹

3. Have there been a lot of complaints about untrained herbalists treating or hurting people

There is ongoing concern about the safety, in particular, of traditional Chinese and Ayurvedic medicines some of which have been found to be misidentified or adulterated with western medicines or heavy metals - see Medicines and Healthcare products Regulatory Agency’s website at (www.mhra.gov.uk). It is also the case that under current regulation (common law), anyone can call themselves a herbalist and set up in practice. In these circumstances it is difficult for the public to distinguish between the good, the bad and the ugly.

If statutory regulation does not go ahead the danger is not from the well trained and competent herbalist. It is from the unregulated internet sites and bogus practitioners who sell dangerous, toxic products to an unsuspecting public. Statutory regulation will enable the public to recognise properly trained and qualified herbalists.

4. Can you explain what statutory registration is?

Statutory regulation is when the state licenses practitioners to practise on the basis that they have the required training and do not have disbaring criminal convictions (e.g. being on the sex-offenders register). In addition, practitioners have to show, by completing required annual continuous professional development programmes, that they are up to speed with their ongoing training. The register of practitioners is held by an independent regulator to whom patients can complain if a patient thinks that he/she has been badly treated. In the case of herbalists, the likely regulator will be The Health Professions Council (HPC) that already regulates a number of health professions such as physiotherapists and occupational therapists. The HPC, in conjunction with the professional herbal associations, sets standards of training, accreditation of training institutions and practice. The HPC would be responsible for any disciplinary proceedings and in the last recourse has the power to strike someone from the register which would mean that person could not call themselves a herbalist (or whatever the regulated and protected title is determined to be –this has not been decided yet).

5. What was the impetus behind the push for statutory registration?

The two main motives, public protection and secondly continued access to a full range of herbal medicines, is explained in the first three answers above.

¹ MHRA website - Ipsos Mori report <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON036071>, Jan 2009.

6. Who is supporting statutory registration?

Statutory regulation is supported by far the majority of UK herbalists and the main professional associations as well as the Health Professions Council and the Prince of Wales Foundation for Integrated Health.

The Department of Health Recently consulted on the proposed statutory regulation (closing date Nov 16 09) of herbal/traditional medicine, TCM and acupuncture practitioners.

This matter has been under consideration for a decade since the call in 2000 from the House of Lords' Select Committee on Science and Technology for the statutory regulation of practitioners of herbal medicine and acupuncture. The Government itself backed statutory regulation of this sector in 2001 and more recently key regulatory bodies, the Health Professions Council (HPC) and the Medicines and Healthcare products Regulatory Agency (MHRA) have both concluded that, like the osteopaths and chiropractors, acupuncture and herbal medicine practitioners should be subject to statutory regulation. As recently as 2006 the DH website recorded that "*The Government is committed to the statutory regulation of herbal medicine, acupuncture and traditional Chinese medicine practitioners.*"²

Over the past eight years the DH has initiated three working groups to look at implementing this policy. All three working parties strongly supported the aim of statutory regulation of this sector. In 2005, the DH ran a public consultation on the statutory regulation of herbal medicine and acupuncture. This registered a 98% response in favour of statutory regulation. As a consequence the DH published a timetable for the statutory regulation of this sector with a section 60 order (the legal process to bring this about) to be published later that year. This timetable has not been adhered to. The Government says it will make a decision on this matter but continues to dilly-dally.

7. Who is opposing statutory registration?

There is a group of scientists and doctors called Sense about Science who are fiercely contesting herbal statutory regulation. Two prominent members are the Professor of Complementary Medicine at Exeter University, Edzard Ernst and a retired Professor of Pharmacology, David Colquhoun. Ernst says that while herbs sometimes are effective, there is no evidence that herbalists, who mix together a number of herbs for individual patients, are effective. Colquhoun says "you can't regulate nonsense". But these are "armchair physicians"; neither of these two men actually sees patients!

On January 7th the Chair of Sense about Science, Lord Taverne, aiming to ridicule the conferring of statutory regulation on herbalists, put down an oral question in the House of Lords asking "*To ask Her Majesty's Government whether, following their proposals to regulate practitioners of alternative medicine, they plan to regulate astrologers.*" His rather puerile attempt at irony made no impact and the health Minister, Baroness Thornton, rather gracefully put Taverne in his place. Before asking the question Taverne gave an interview to the political website *ePolitix* that gives a flavour of the kind of attack to which herbalists are being subjected. Taverne's assault was responded to by Michael McIntyre. His interview and McIntyre's response follow.

² DH Workforce Update

<file:///c:/Users/Mic/Documents/EHPA/Workforce%20update%20%20The%20Department%20of%20Health%20-%20P&G%20Human%20resources%20and%20training.htm>

Lord Taverne: “My parliamentary question about regulating astrologers is inspired by the government's proposed statutory regulation of alternative medicine. The government proposes to regulate practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems.

This is clearly a response to intense lobbying by Prince Charles' Foundation for Integrated Medicine.

The proposal is strongly opposed by Sense About Science (of which I am chairman), the Medical Research Council, the Academy of Medical Royal Colleges, the Institute of Biomedical science, the Medical Schools Council, the Physiological Society and the Royal College of Pathologists.

It would give practitioners of alternative medicine a spurious respectability, as being sanctioned by official regulation, which implies that their practices are evidence-based when there is little if any scientific evidence in their support.

They offer accounts of basic physiology and pharmacology that are highly implausible. In fact, they have about as much scientific basis as astrology. So why not add parapsychologists or astrologers to the list?

In defence of alternative medicine systems, it is argued that they are popular. But astrology is even more popular. In fact, pseudo-science generally is fashionable.

Several universities actually give 'science' degrees in homeopathy, ayurveda and reflexology and other forms of alternative medicine.

It is also argued that many of the practices must be effective because they have been around for centuries. So has witchcraft, or the belief that prayer can cure disease. But medicine is not like a piece of antique furniture, which becomes more valuable with age.

If the government is worried about patient safety it should require practitioners of alternative medicine to undergo conventional medical training. It should take a firm stand in favour of science-based policy, not appear to legitimise quackery.

Michael McIntyre responding: As chairman of 'Sense about Science', the least we should expect from Lord Taverne is to write accurately and impartially. But his piece on the regulation of practitioners of acupuncture and herbal medicine is ill-informed, highly opinionated and surprisingly inaccurate. Worst of all, by arguing against regulation, Taverne actually puts the public at serious risk, since regulation will ensure the proper training of these practitioners and the quality and safety of herbal products they use. It is clearly in the public interest for statutory regulation to go ahead.

Taverne says that the government's move to statutorily regulate herbal medicine and acupuncture is a response to lobbying from Prince Charles' Foundation for Integrated Medicine (sic), but this is not true. As a Member of the House of Lords, Taverne should know that the impetus for statutory regulation actually came from the House of Lords' select committee on science and technology (on which sat several eminent scientists and doctors), which recommended in 2000 that acupuncture and herbal medicine should be statutorily regulated as soon as possible. In the light of this recommendation, the government agreed in 2001 that statutory regulation should go ahead.

Over the past eight years the Department of Health has initiated three working groups to look at implementing this policy. All three working parties strongly supported the aim of statutory regulation of this sector. In 2005, the DoH ran a public consultation on it. This registered a 98 per cent response in favour of statutory regulation. Given the thoroughness with which the DoH has examined this issue over the years, it is questionable whether the recent second public consultation was a good use of public money.

Taverne also says: "If the government is worried about patient safety it should require practitioners of alternative medicine to undergo conventional medical training", but here too he displays ignorance. The agreed training in herbal medicine in the UK requires practitioners to be well versed in a wide range of conventional medical instruction including differential diagnosis and pharmacology. Taverne opines that official regulation would give practitioners "a spurious respectability, as being sanctioned by official regulation, which implies that

their practices are evidence-based, when there is little if any scientific evidence in their support". Here Taverne clearly misunderstands the role of regulation. Regulation is not a badge of rank but is all about public protection.

Herbal medicine is enormously popular. Recent research by Ipsos MORI for the Medicines and Healthcare products Regulatory Agency (MHRA) has found that millions of people in the UK use herbal medicines, and that more than a quarter of the population had bought herbal medicines over the counter in the previous two years, with 1 in 12 consulting a practitioner of Western herbal medicine, and about 1 in 20 consulting a practitioner of traditional Chinese medicine. It also noted that 77 per cent of adults agree it is important that herbal medicines are regulated, with this figure rising to 87 per cent among regular users of herbal medicines (defined as those who have used a herbal medicine within the last two years). Is Taverne really saying that the public is foolish in its use of herbal medicine and in its clearly expressed wish to have its practitioners properly regulated?

As to evidence; those in glass houses should not throw stones. Taverne clearly assumes that mainstream medical practice is mostly based on evidence-based medicine. Recent findings published in the BMJ's online Journal Clinical Evidence shows that far from having a complete evidence base, only about 13 per cent of 2,500 medical treatments surveyed are rated as beneficial, with 46 per cent "of unknown effectiveness". But there is plenty of evidence on the efficacy of herbal medicine; there are scores of scientific papers on the efficacy of commonly used herbal medicines such as ginger, garlic, hawthorn etc. Indeed, who could doubt the medical efficacy of botanic medicines, since many modern drugs are derived from plant medicines?

Interestingly, it is not just plant medicines themselves that modern medicine has exploited: more recently, it has come to adopt a strategy central to traditional herbal treatment which harnesses the healing potential of several medicaments together for their synergistic effect, rather than using one herb at a time. These days it is common for doctors to prescribe a number of drugs together, as seen in the treatment of a wide range of serious diseases like HIV, Aids, TB, malaria, diabetes, hypertension, cancer, MRSA etc.

Pharmacologists now acknowledge that the individual actions of one drug are subject to modification by a second drug and that multi-drug regimens ('combination therapy') may confer unique and beneficial new actions that do not occur when using each drug on its own. Moreover, it has become evident that combination therapy can frequently attain the same therapeutic effect as when using a single drug, but with fewer deleterious side effects. Last week scientists announced that they had found that a combination of pomegranate rind, vitamin C and a metal salt gave good results in combating the MRSA superbug.

Perhaps modern medicine has still much to learn from herbal medicine. The frank protectionism Taverne and his colleagues now display is yet another way that he and 'Sense about Science' ill-serve the public interest.

8. Do you feel it will be in the best interest of consumers to have statutory registration of herbalists or do you think it will impede access to herbalists?

There is no reason to believe that statutory regulation will impede access to herbalists and it is clear that without it, for reasons explained above, the public will lose access to a wide range of herbal medicines.

9. How would the different outcomes affect the common law statute of King Henry VIII?

Herbalists often cite the common law statute of Henry V 111 (known as The Herbalists' Charter). But many herbalists are not aware that from 1941 to 1968 under the 1941 UK Pharmacy Act, it was actually technically illegal for UK herbalists to treat their patients. The 1968 Medicines Act with its Section 12(1) and 12(2) mentioned above once more made it legal for herbalists to prescribe. Now we are losing Section 12(2) to European legislation, more than ever we need a sound legal basis for our practice. Statutory regulation will give us this.

10. Are professional herbalists united in their position on SSR? If not, why not?

Most are. A few are not. They consider that herbalists have a right to practise without any outside legal restraint and that any state interference is unwarranted. Unfortunately, with some 2000 herbal practitioners in the UK, working in an environment which is increasingly regulated, it is not realistic for herbal practice to survive in the long term without a firm legal basis. The introduction of the THMPD will see the loss of many medicines unless herbalists attain statutory regulation – something for which the National Institute of Medical Herbalists, the oldest body of herbal practitioners in the UK, has struggled for nearly a century. And what's more the public agree with regulation. The Ipsos Mori report quoted in the answer to Question 2 found 77% of adults agree it is important that herbal medicines are regulated, with this figure rising to 87% among regular users of herbal medicines (defined as those who have used a herbal medicine within the last 2 years).

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