

Response to questions from Lindsay Stafford from Michael McIntyre
Chair European Herbal and Traditional Medicine Practitioners
Association
2/19/2010

Questions:

- 1) You write that a THMPD license is not a viable option for herbal products used for specific patients, such as pills, capsules, mixtures and ointments because practitioners cannot afford the cost of a license. Are you saying that under the THMPD, these herbal products combined and mixed by practitioners will need to have product licenses? And/or that the practitioners will also need a license because they will then be considered manufacturers (and manufacturers are required to be licensed under the THMPD and UK scheme). Would these not be considered non-industrial produced medicines made up on the premises, thus requiring no license?

Lindsay, I am not aware of having written that THMPD licenses are not viable because practitioners cannot afford the cost of a license. Please can you tell me when I have said this? Your question is rather confusing but I hope my answer will tell you what you want to know.

THMPD licensing

THMPD licenses (AKA Traditional Herbal Registration – THR) are designed for direct over-the-counter sale to the public without any professional intervention or advice. They are limited to treatment of mild and self-limiting conditions such as the common cold and “the temporary relief of sleep disturbances” and carry indications to inform the purchaser as to the condition(s) that particular herbal medicine may be used to treat. When the Medicines and Healthcare products Regulatory Agency (MHRA) – the UK equivalent of the FDA- put out a guidance note a few years ago as to which conditions might be treatable by means of THR herbal products, it gave examples of only two cardiovascular conditions that might qualify for THR licenses – the treatment of chilblains (*perniosis*) and piles (*haemorrhoids*).¹ However, herbal practitioners treat a much greater range of cardiovascular conditions than these and vary prescriptions to take account of individual needs.

The fundamental problem for practitioners who see patients face-to-face is that THR remedies are not sufficiently flexible or precise enough to enable the practitioner to treat a range of conditions on an individual basis. For example, one patient with poor circulation may be treated primarily with a mixture of circulatory stimulants, whilst a second patient with the same complaint might be prescribed herbal nervines and relaxants because the fundamental problem in this case is sympathetic nervous system predominance caused by chronic anxiety. THR products would not answer the specific needs of these individual patients.

Herbal practitioners utilize of the synergistic effects of plant medicines to treat their patients and the knowledge of how to mix medicinal plants to best advantage is a central feature of most traditional systems of herbal medicine the world over. Many traditional Chinese, Ayurvedic and Tibetan herbal formulae contain combinations of a dozen or more plant medicines and western herbalists also customarily combine several herbs together in individualized prescriptions. These combinations are often the result of hundreds of years of experience of working with plant medicines. Ironically, in recent years conventional medicine has begun to recognize the value of synergy in medicine via the common practice of combining drugs to

¹ See MHRA document “MHRA doc examples of permitted indications under THMPD” on EHTPA website, http://www.ehpa.eu/medicines_legislation/index.html.

treat 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.² Over the last decade or so, it has thus been established that combination drug therapy can deliver greater therapeutic effect than can be achieved with a single conventional medicine. 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.³ For these reasons, the authorities should surely be providing legal frameworks to enable complex mixtures of herbs to be placed on the market, but they are not.

For the most part, THR products sold over the counter are limited to one or two herbs mixed together due to the difficulties of applying to more complex herbal mixtures the same quality controls that are designed and used to assay conventional pharmaceuticals. The strictures of the THMPD quality assurance as well as the considerable time and cost to obtain a license makes this an unfeasible route for the provision of 12(1) individualized prescriptions that are likely to change as individual treatment progresses and to contain several herbs used together. Presumably for these reasons, the Herbal Medicinal Products Committee (HMPC) within the European Medicines Agency (EMA) has recently acknowledged that the THMPD has not provided a suitable basis for the supply and sale of traditional Chinese and Ayurvedic medicine and other traditional medicine systems.⁴ It states:

“Medical traditions such as those mentioned above (i.e. Chinese, Ayurvedic and other traditional medicine systems) are based on a holistic approach and the set of requirements for the simplified registration procedure under Directive 2004/24/EC (AKA the THMPD) is not appropriate for a global regulation of such medical practices. The regulation of such traditions would demand a different approach from that introduced by Directive 2004/24/EC. Therefore, the Commission does not envisage extending the scope of the simplified registration procedure to cover traditional medical systems as such. Nevertheless, independently of this report, the suitability of a separate legal framework for products of certain traditions should be assessed.”

Thus it can be seen that the THR system is completely inadequate to provide the majority of herbal medicine that practitioners of all herbal traditions use on a daily basis.

Practitioner compounded herbal medicines (custom-made herbal medicines)

Herbal medicines made up by practitioners on their own premises will still be permitted to be exempt from licensing after April 2011 when the THMPD is fully implemented. This exemption from licensing is granted under Section 12(1) of the UK Medicines Act of 1968. The problem here is that this process is largely unregulated and is open to anyone to use regardless of training as the statute does not define a “herbalist”; indeed, the statute doesn’t mention the word “herbalist”. The only strictures laid down by the 1968 statute is that the person carrying out the supply or sale of herbs to a patient must do so after a personal consultation and in premises capable of being locked from the public (i.e. not a market stall) and on premises where “the person carrying on the business is the occupier”. Whereas this

² Toews ML, Bylund DB. Pharmacologic principles for combination therapy. *Proc Am Thorac Soc.* 2005;2(4):282-9; discussion 290-1. Review.

³ Reid JL. Pharmacokinetic and pharmacodynamic aspects of the choice of components of combination therapy. *J Hum Hypertens* 1995;9:S19–S23

⁴ The 2008 Communication from the Commission to the Council and the European Parliament concerning the Report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to traditional herbal medicinal products (Document on the basis of Article 16i of Directive 2001/83/EC).

was considered adequate in 1968 when there were a handful of herbalists working in the UK, today it certainly does not seem sufficient when every other form of supply of food and medicine is regulated by statute and there are some 3000 herbal practitioners working throughout the UK.

In February 2010, very sadly, UK national papers, radio and TV carried lurid headlines about the case of a Chinese woman tried in the Old Bailey – the UK’s most famous law court, who had prescribed the same Chinese pills to a patient for five years that contained a banned herb, *Aristolochia fangchi* (containing the kidney toxin aristolochic acid). As a result of taking the pills the patient’s kidneys ceased to function, she developed cancer and is now dependent on dialysis, currently awaiting a kidney transplant. The London *Times* headline read “*Herbalist’s tablets caused terrible harm*”.⁵

Unfortunately, this is not the only public alarm of its kind. In these circumstances, it is hardly surprising that there are calls for herbalists to be regulated. In fact, this goes back to 2000 when the prestigious House of Lords’ Select Committee on Science and Technology called for herbalists and herbal products to be statutorily regulated.⁶ Subsequently, two further Department of Health Working Groups also called for herbalists and herbal products to be regulated.^{7 8}

The outlook for Section 12(1) exemptions from medicines licensing for herbal practitioners working in their own dispensaries and clinics, appears bleak in the long term because it is an incongruity across the EU. Once the THMPD comes in April next year and all over-the-counter herbal medicines are licensed, the 12(1) exemption will increasingly be seen as a legal anomaly.

In the UK, we are working in an environment which more and more champions public safety and informed choice, and is increasingly regulated. It is not realistic to expect that herbal practice can survive in the long term without a firm legal basis. The public are confused by the many qualifications that people use to justify practice and find it hard to get redress should anything go badly with their treatment. In these circumstances, our dispensaries are likely to be subject to growing unsympathetic scrutiny and regulation by a number of officials from environmental health or trading standard officers.

On the other hand, if herbalists are granted statutory regulation, it is proposed that the profession would govern its own standards for running herbal dispensaries.⁹ While the vast majority of herbalists practice with high professional standards, regulation is about protection of the public across the board. When the Department of Health published the results of a public consultation in 2005, it showed overwhelming public support for statutory regulation

⁵ *The Times* Feb 18th 2010 page 15.

⁶ <http://www.publications.parliament.uk/pa/ld199900/ldselect/ldscitech/123/12301.htm>.

⁷ http://www.users.globalnet.co.uk/~ehpa/pdfs/hmrwg_report.pdf.

⁸ http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_103567.

⁹ Report to Ministers from the Department of Health steering group on the statutory regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK.

<http://www.dh.gov.uk/en/AdvanceSearchResult/index.htm?searchTerms=Steering+Group+acupuncture+herbal+medicine>.

of herbal practitioners.¹⁰ Last year an Ipsos MORI report commissioned by the found that 77% of adults in the UK agree it is important that herbal medicines are regulated.¹¹

Statutory regulation may be unacceptable to those who want no interference in their practice but without it there may well be no practice as we know it to protect. The Old Bailey court case provides a powerful argument for regulation.

- 2) It seems that EHPA and other pro-regulatory groups are arguing that it is necessary to license herbalists and other TCM practitioners so that they will continue to have access to their herbal medicines. But beginning in April of 2011, won't it be true that if a medicine does not obtain either a traditional-use registration or a full medicine license, it will be unavailable whether or not the practitioner is statutory-regulated? And if the herbal product is made on the premises, won't require a license? I'm trying to understand how regulation of practitioners will provide continued access to a full range of herbal medicines.

If herbal practitioners are statutorily regulated they can be considered "authorized health professionals" in European terms. Under Article 5. 1 of the main European Medicines Directive 2001/83/EC this will give them the right to commission herbal medicines from third parties to meet the needs of individual patients without the need for a full marketing authorization (medicines license). There are two reason why this is an essential requirement for herbal practice.

Firstly, for manufactured complex remedies such as are normal in Ayurvedic and Traditional Chinese Medicine there will be no other legal way to supply them to patients.

Secondly many practitioners work in premises which do not have room for their own herbal pharmacy and over the past thirty years the practice has evolved of using third party prescription services - often provided by the same companies that produce and supply the tinctures and other medicines in bulk. These suppliers send the individualized prescriptions direct to patients at the request of a practitioner. At present, this is legal under Section 12(2) of the 1968 Medicines Act but will cease to be so after April 2011 when the THMPD and its THR replace Section 12(2). After April 2011, the only way practitioners can continue to use these third-party prescription services is if they gain "authorized health professional" status via statutory regulation. The reason for this is explained above. If statutory regulation does not happen, there will be serious consequences for herbal practitioners.

For example, when we asked the National Institute of Medical Herbalists about the impact of loss of this third party supply we heard the from the NIMH that a significant number of members responding to this enquiry said that they are using a herbal dispensary service and many of them said it was essential to their business. We were told "*from this it can be seen that the loss of third-party supply is going to have very serious implications for the viability of our members' practices*".¹² The Register of Chinese Herbal Medicine told us it estimated "*that at least 80% of members are heavily reliant on external dispensaries and that at least 50% could go out of business without access to them. This is probably a conservative*

¹⁰ Department of Health , *Statutory regulation of herbal medicine and acupuncture: Report on the consultation, 2005* - http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_4103372.

¹¹ <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON036071>

¹² See <http://www.ehpa.eu/pdf/home/news/Regulatory-Impact-of-Failure-to-Gain-SR-on-Herbal-Sector.pdf>.

estimate since the number of practitioners put out of business might be nearer 60 -70%.”¹³ It also appears from our survey that many herbal suppliers are going to lose essential turnover as a result of the loss of third party supply and this could affect their financial viability. A typical response was from the herb company “Panacea”. It told us “Panacea dispensary is a third party supplier to practitioners for individual patients. This is approximately 20% of Panacea’s total turnover and equates to the likely loss of 1 full-time and 4 part-time jobs. The loss of this turnover would have a significant impact on our business and our viability in these difficult economic times.”¹⁴

It will still be the case that herbal practitioners will still be able to make their own prescriptions from simple herbal starting materials under section 12(1) because they are deemed as not “industrially produced” in European Medicines legislation. However, because of the requirement for this exemption to be tied to the premises where “the person carrying on the business is the occupier”, non-industrially produced prescriptions from a third party outside of those premises will not qualify for an exemption from licensing.

- 3) Do you agree that most herbalists already make up their herbal preparations on the premises, so the THMPD will not affect the majority of herbalists? Is this a different situation for Ayurvedic and TCM practitioners?

I have answered this above- explaining that it will affect herbalists of all traditions. Many TCM and Ayurvedic practitioners use patent medicines as well as dried herb prescriptions and these are supplied by third parties. After April 2011 this will only be possible if the practitioners have “authorized health professional status” via statutory regulation. This will then continue under license from the MHRA.

- 4) You say in your interview that statutory regulation will enable patients to obtain their usual medicines because 2001/83/EC states that authorized health professionals can commission products and finished prescriptions from third-party suppliers? Are you also say that these commissioned products and finished prescriptions from 3rd-party suppliers will not need a full medicine license or traditional-use registration?

Yes, I am saying that because there is already a special dispensation for doctors and dentists to prescribe “specials” – that is medicines without a license for the needs of individual patients that cannot be met by existing licensed medicines. This is under Article 5.1 of Directive 2001/83/EC I mentioned earlier. It is proposed by the MHRA that once herbalists are statutorily regulated, they too will be legally considered “authorized health professionals” and thus able to supply finished herbal medicines to meet the needs of individual patients exempt from licensing.¹⁵ Herbal medicines made this way would not need a THR or a full marketing authorization (license).

- 5) Some anti-regulatory, pro-herbalists groups say that there is no link between the THMPD and the regulation of practitioners. Is this true? Do you agree?

¹³ *Ibid*

¹⁴ *Ibid*

¹⁵ MHRA Discussion paper: no 6Reforms of s12(1) of the Medicines Act 1968: the regulation of unlicensed herbal medicines commissioned by a registered practitioner from a third party to meet the needs of individual patients.

<http://www.mhra.gov.uk/SearchHelp/Search/Searchresults/index.htm?within=Yes&keywords=Herbal+individual+needs>.

Lindsay, this is an interesting turn of phrase. As you have “anti-regulatory herbalists” down as “pro-herbalists” does this mean if we argue for regulation does that make us “anti-herbalists”? I think not.
I and my colleagues are definitely pro herbal medicine...

I have explained that there is a link. Many practitioners and their suppliers have been dependent on Section 12(2) that allows third party supply. This will be abolished by the full implementation of the THMPD. As I have made clear, this will adversely affect many practitioners and suppliers. Moreover, the 12(1) exemption for licensing is open to anyone to use and, as I have also explained, there is no legal definition of who can use this exemption. This allows anyone, irrespective of training and qualification, access to the potent herbs available to users of 12(1) under a separate Statutory Instrument (SI 2130). These herbs include for example belladonna and ephedra. It is unlikely that this unregulated open access will be allowed to continue indefinitely. For all these reasons, statutory regulation seems the best option which will give our own profession some say over its development and destiny.

- 6) If professional herbal associations are already active in licensing, why is it necessary to have the state join the process?

In the UK the legal framework for regulation of medicines and practitioners is different from that of the USA. Professional associations do not have any power to license or say who can or cannot use a herb. This is entirely a matter for the UK Government and the European Commission. Medicines law is set at EU level whilst regulation of health professionals is determined by each Member State (the UK Government in the UK). Statutory regulation would protect the title as well as the function of herbal practitioners. The title of herbal practitioner (the exact title is yet to be decided) would be restricted to those on the statutory register and it would be illegal for anyone not on the register to use this. It is also proposed that only those of the statutory regulation would be able to prescribe to patients on an individual basis (i.e. use Section 12(1) of the 1968 Medicines Act) and so this, in effect, would also regulate function. Proper qualification and continuous professional development would be requirements for acceptance onto the statutory register as well as a satisfactory criminal record check. These measures would protect the public from bogus, backstreet operators without training or acceptable standards of practice.

The recent Dept of Health (DH) Consultation Document (CD) offers a number of possibilities if statutory regulation does not occur.¹⁶ These are as follows, together with their implications.

- Abolishing Section 12(1) of the Medicines Act of 1968. This would mean that herbal practice would be limited to using herbal remedies available OTC under the traditional herbal registration scheme (THR) via the Traditional Herbal Medicinal Products Directive (THMPD). In effect for reasons explained above, this would spell the end of herbal practice for all who are not statutorily regulated such as doctors.
- The second possibility envisaged is voluntary regulation (VR) which is similar to what exists now except that the DH has made it plain that it would prefer all practitioners wishing to work with NHS patients to sign up to voluntary regulation to be under its sponsored umbrella body the CNHC see:
http://www.fih.org.uk/events/fih_integrated_health_events/delivering.html.

¹⁶ 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 2009. http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_103567.

- VR would not enable any practitioners to access third party supplied or manufactured finished herbal medicines or prescriptions after April 2011 when the THMPD comes in. As previously explained, will have dire consequences for those who have no dispensaries within their practices as the 12(1) exemption does not apply to provision from a dispensary that is off the premises of which, as Section 12(1) of Medicines Act of 1968 says, the “person carrying on the business is the occupier”. Suppliers may go out of business too as they will lose third party supply business. Training at Universities might be adversely affected too. The University of Central Lancashire (UCLan) has recently said that it will only run courses that feed into statutorily regulated professions. This has led to closure of herbal courses that were validated by UCLan as herbalists do not have statutory regulation despite a Government commitment to this dating back to 2001.
- Voluntary regulation will not prevent anyone who chooses to practice outside of the voluntary regulatory regime from doing so or prevent anyone from continuing to practice even though removed from the voluntary register and will therefore offer limited, if any, real public protection. There are several professional associations representing herbal practitioners and some have low standards of training and regulation. How can the public know who is well trained and regulated or be assured that herbal medicines have quality assurance in an unregulated sector?
- Another possibility trailed by the CD is that of statutory licensing. It is explained within the CD that a “light touch” licensing regime would be based on the model employed by the Security Industry Authority (SIA). This would involve licensing anyone who has an accredited qualification and has also undergone a satisfactory criminal record.
- The SIA currently licenses bodyguards, bouncers and wheel clampers and hardly seems the model on which to base the appropriate regulation of health professionals. There are serious shortcomings with regard to such statutory licensing. Whilst it would carry out a criminal record check, it would not operate formal fitness to practice procedures consisting of an investigation committee, panel hearings and an appeal to an independent body as is usual when examining such fitness to practice matters. Nor would such a licensing system supervise continuous professional development (CPD) schemes, maintain quality and standards in the profession (e.g. regulate accreditation of training programs) or encourage advancement of the profession in terms of practice and research. It would not act in any way to advise or direct systems to ensure the quality control of herbal medicines provided by herbal practitioners using 12(1) provision. In addition, it would fail to provide a means by which herbal practitioners could access herbal products made by third parties under Article 5.1 of the main EU Medicines Directive, 2001/83/EC with the ramifications mentioned above. The EHTPA has rejected the possibility of this kind of licensing in its response to the DH Consultation Document.¹⁷
- In short, a statutory licensing system, as opposed to statutory regulation, would fail to deliver a thoroughly professional body of practitioners who could work side by side with other similarly regulated health practitioners for the public good. It will relegate herbal/traditional medicine to a partial and ineffective regulatory scheme that clearly distances herbal medicine from healthcare professions that are statutorily regulated making it impossible for statutorily regulated health professionals to make referrals to practitioners within this sector. This would make communication between professionals difficult which will not be in patients’ best interests.

¹⁷ http://www.ehpa.eu/pdf/home/EHTPA_response_to_DH_Consultation_Document.pdf.

- On the other hand, statutory regulation appears by far the best option put forward in the DH CD. It will protect the public from poor or failing practitioners. It will enable third party supply via Article 5.1 of Directive 2001/83/EC and give herbal medicine practitioners a secure legal basis for their practice. It will encourage university standard training and ensure independent accreditation of training institutions and continuous professional development. The Health Professions Council, one of the UK's statutory regulatory bodies, has written to the UK Secretary of State for Health recommending that it should statutorily regulate the herbal profession and positively supported herbal statutory regulation in its response to the DH CD.¹⁸ In the UK, chiropractors and osteopaths have achieved statutory regulation and this has immeasurably strengthened their professions.

- 7) Do you agree that practitioners who are not credible, will lose their patient base and go out of business anyway, meaning that the non-state regulated profession weeds out safety concerns on its own?

Why would anyone think that? There has been no state regulation to date and the herbal practitioner sector has grown enormously in the last decade. The public are confused by all those now claiming rights to prescribe herbs and sadly accidents like the one that has just been reported now are not infrequent. You can see this for yourself if you look at postings on the MHRA website – the recent Old Bailey case being just one example. At the end of this trial the Judge said that the sale of traditional Chinese medicines was totally unregulated in Britain and so there was no evidence that Wu (the supplier) knew of the herbal tablets' potential harm. The Judge said he accepted Wu did not know she was breaking the law. Although the MHRA did their best to try and make sure everybody knew about the dangers and about the regulations, it is not a foolproof system. He went on to say, "*In this country, if you are operating a business like Miss Wu's of supplying traditional Chinese medicine, there is no system in place whatever to make you aware of these regulations.*"¹⁹

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¹⁸ http://www.ehpa.eu/pdf/home/HPC_response_to_joint_consultation_on_CAM_steering_group_report.pdf.

¹⁹ <http://uk.reuters.com/article/idUKTRE61G3N420100217?pageNumber=1&virtualBrandChannel=0>.