

The clear & present need for the statutory regulation of UK herbal practitioners

Introduction

For more than a decade, the main UK professional associations representing herbal medicine practitioners practising western herbal medicine, Chinese herbal medicine, traditional Tibetan medicine and Ayurvedic medicine have strongly supported statutory regulation of herbalists in the UK.¹

As the UK Department of Health and Medicines and Healthcare products Regulatory Agency are currently hosting a working group chaired by the Deputy Chief Medical Officer for Health for England to review this matter again, it is timely to reiterate the many reasons why statutory regulation is so important for the future development of herbal medicine practice in the UK.

This paper explains the reasons why in 2014 statutory regulation is wholly in the public interest and a necessity for any healthcare profession practising internal medicine. Statutory regulation provides the best chance for herbal practitioners to continue to access the full range of herbs they currently prescribe. In addition, statutory regulation will ensure that the public are protected from poorly trained or bogus practitioners and from substandard herbal remedies. Statutory regulation will identify professionals able to assure the quality of herbal treatment for the public. Without statutory regulation of this sector the public is at considerable risk and the UK as a whole loses the chance of realising the full potential of herbal medicine.

Comment on legislation

- Current UK legislation provides a weak legal basis for herbal practice. The fact that there is no description or definition in law of who is a herbalist means that any member of the public can call themselves a herbalist. The loss of access to many herbal medicines via Section 12.2 of the 1968 Medicines Act is substantial. The lack of professional recognition via statutory regulation means that there is no opportunity for the herbal profession to gain special access as an ‘authorised health-care professional’ to third party supplied medicines eg via article 5.1 of Directive 2001/83/EC (‘specials provision’) or article 3.1 (‘magistral formulae’). In addition, the European Union is seeking to harmonise professional qualifications across the EU via the Directive 2005/36/EC on the Recognition of Professional Qualifications. Article 6 of this Directive declares ‘In order to promote the free movement of professionals, while ensuring an adequate level of qualification, various professional associations and organisations or Member States should be able to propose common platforms at European level’. At present, recognition of medical specialities can only

¹ Currently supported by the Ayurvedic Practitioners Association, Register of Chinese Herbal Medicine, the British Association of Traditional Tibetan Medicine, the College of Practitioners of Phytotherapy, the National Institute of Medical Herbalists, the Unified Register of Herbal Practitioners and the Association of Traditional Chinese Medicine.

occur when common to at least two fifths of Member States. However, it is anticipated that in time, a complete harmonisation of professional qualifications will occur, the prerequisite of which must be legal recognition of a profession i.e. in the case of herbalists being considered ‘an authorised health professional’ via statutory regulation. Yet as things stand, herbal practice is not legally recognised as a profession in the UK (see Addendum B for further detail).

Statutory regulation can provide availability of a full range of herbal products

- Statutory regulation will provide a means of establishing third party supply on the basis that herbal practitioners request third party suppliers to make up individual herbal prescriptions for named patients (after a personal consultation). These prescriptions might be dispensed mixtures of dried herbs or encapsulated mixtures of herbal powders or pills or mixtures of herbal tinctures or fluid or stabilised water extracts of herbs.² This facility would answer the need for new practitioners who did not have access to a herbal dispensary at their practice to have their prescriptions supplied by third party suppliers. It would also meet the needs of practitioners who, following a consultation, needed mixtures of formulations made up on a small scale for the needs of individual patients by dedicated herbal dispensaries in optimum conditions. *Prima facie* it appears such products would be wholly in keeping with Article 5.1 of Directive 2001/83/EC (specials provision).^{3,4}
- There are currently a number of potent herbal medicines available to herbal practitioners for prescription on an individual basis such as *Ephedra sinica*, *Lobelia inflata*, *Atropa belladonna* etc. under Schedule 20 of the Human Medicines Regulations 2012. This Schedule is a transcription of Schedule 111 (SI 2130 Retail Sale or Supply of Herbal Remedies) Order 1977 of the Medicines Act of 1968. It is possible that in the long term herbalists, who are undefined in law, may no longer be permitted to enjoy access to these remedies as there is currently no legal way that herbalists can be distinguished from unqualified members of the public. Statutory regulation will safeguard access to these and other herbal medicines that are considered too potent for public sale or use.

Training and continuous professional development (CPD)

- Statutory regulation will provide essential prerequisites for the development of herbal practice which include a common standard of training delivered at a level that ensures that practitioners know when to refer and when and how to treat. Any voluntary system of regulation is in danger of being undermined by training standards being reduced to the lowest common denominator. Statutory regulation ensures that common standards of training can be legally set and enforced by the regulator as can rigorous CPD programmes across the profession.

Public assurance regarding the probity of practitioners via protection of title

- Statutory regulation alone can legally provide protection of title to ensure that only those qualified to practise herbal medicine can lawfully do so. An enforceable fitness to practise (FTP) regime by the designated statutory regulator, the Health and Care

² Including the following - preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

³ Article 5.1 says: ‘A Member State may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility.’

⁴ The EHTPA has taken expert independent legal advice that corroborates that this option is legally viable.

Professions Council (HCPC), will provide security for patients seeking herbal treatment.⁵ The HCPC has the legal powers to enforce due process, including being able to compel disclosure of information and the attendance of witnesses at hearings.⁶ Voluntary regulation can provide no such security for patients consulting herbalists.

Voluntary versus statutory regulation

- Of course, no one wants any more regulation than necessary. Voluntary regulation has been the model that has served herbal medicine until now. However, as the profession grows and voluntary registers and training programmes proliferate, it becomes increasingly difficult to maintain excellent standards of training and practice across the board. As mentioned above, shorter, cheaper training may attract students away from well run programmes because those seeking herbal training may be unaware of the range of proficiencies that need to be acquired in order to practise safely and effectively. Moreover, as discussed below, any sanction applied by a voluntary register can be negated if the practitioner in question leaves the professional association to practise independently.
- Voluntary registers may now apply for accreditation by the Professional Standards Authority for Health and Social Care (PSA) set up under the Health and Social Care Act 2012 to act as an administrator of voluntary registers.⁷ The Department of Health (DH) appears to be keen on this type of voluntary regulation for CAM professions and the PSA has recently given a presentation to the DH Herbal Working Group considering the way forward on herbal regulation. However, regulation by the PSA appears wholly unconvincing. Because the PSA is also the regulator of all the UK statutory regulators such as the GMC and the Nursing and Midwifery Council, there is understandable public confusion when it comes to the PSA's role in undertaking voluntary regulation. In reality this task, has nothing to do with the PSA's statutory regulatory work and professional registers opting to operate within the PSA still remain wholly voluntary. In fact, the PSA, like any other voluntary register, provides no protection of title since disbarred practitioners can simply avoid intervention by resigning and continuing to practise outside of the voluntary scheme. There are cases where this has indeed occurred thereby undermining all the efforts of the current voluntary registers to set and enforce standards of education, competence and professional behaviour
- Such an avoidance strategy is not possible once a profession is statutorily regulated as a practitioner removed from the statutory register cannot lawfully practise. Removal from the Health and Care Professions Council (HCPC) register is a serious penalty as the practitioner is no longer able to use the protected title. Use of a protected title or any other ersatz title used to suggest bone fide statutory registration by a practitioner who is not registered with the HCPC can lead to prosecution and a fine of up to £5,000. The HCPC is an experienced statutory regulator currently regulating 16 health and care professions and is generally acknowledged as having a light touch requiring relatively little paperwork on behalf of registrants (for comparative costs see below).

⁵ The HCPC has been designated as the preferred statutory regulator in the event of statutory. In response the HCPC has written to the Secretary of State for Health stating that it would welcome the opportunity to be the regulator for herbal practitioners. See <http://www.hpc-uk.org/mediaandevents/statements/traditionalmedicine/index.asp?printerfriendly=1>

⁶ See <http://www.hpc-uk.org/complaints/fitnesstopractise/furtherinfo/>; Annual Report <http://www.hpc-uk.org/assets/documents/100042D7Fitnessstopractiseannualreport2013.pdf>; Prosecution Policy <http://www.hpc-uk.org/aboutregistration/protectedtitles/>

⁷ See Accredited Voluntary Registers: Standards for organisations holding a voluntary register for health and social care occupations. Professional Standards Authority 2013. www.professionalstandards.org.uk

Protection of title via statutory regulation

- The Pittilo Report recommended to government that the prescribing of herbal medicines for individual patients under section 12.1 of the 1968 Medicines Act (now Regulation 3 of the Human Medicines Regulations 2012) should be limited to statutory regulated practitioners.⁸ This would effectively protect the function as well as title of the herbalist thereby providing further public assurance about the competence of herbal practitioners. Such protection of function can only be achieved via statutory regulation.

Costs of voluntary versus statutory regulation

The costs of accreditation of voluntary registers by the PSA are steep compared to those for statutory regulation and seemingly discriminate against smaller professional organisations. The PSA's Annual Voluntary Regulation scheme requires that applicant organisations must pay a minimum fee of £12,000 when they apply and, if accredited, a minimum fee of £9,000 to renew their accreditation annually. There would also be extra costs in compliance with their recommendations, for example in management and updating of the online register. The PSA says that it reserves the right to charge more 'according to variables that reflect complexity and additional resources to assess a particular organisation'. In contrast, the Health and Care Professions Council (HCPC), designated as the statutory regulator if statutory regulation goes ahead, charges just £80 per person a year with a £56 charge extra for processing the initial application. These fees are paid by each registering individual and so practitioners who belong to the smaller current voluntary registers are not disadvantaged.

Ensuring quality herbal supplies

- Statutory regulation provides a means of ensuring the use of high quality herbal products by herbalists in that it makes it possible for the profession to better ensure the correct identification and quality of medicinal plant material prescribed by practitioners, free from contamination or adulteration. Any scheme run outside statutory regulation will always leave participating herbal suppliers at risk of being financially undercut by companies or internet sources with poor quality assurance and standards.

Statutory regulation permits herbal practitioners to initiate and run research programs

- Statutory regulation will enable herbal researchers to initiate and take charge of their own research programmes. As things stand, a herbalist cannot legally fulfil the role of Chief Investigator on a clinical trial.⁹ Only authorised health professionals can do this which means that a herbalist cannot take primary responsibility for the trial. This puts herbalists in a supportive/subordinate role having to rely on qualified researchers from outside of the profession. Statutory regulation would permit a suitably qualified herbal practitioner to take primary responsibility for a research programme involving a clinical trial.

Statutory regulation qualification for medical insurance reimbursements

⁸ Pittilo M. *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. The report (section 27 p.22) says, 'On the basis of these considerations we recommend that use of Section 12(1) of the Medicines Act of 1968 should be restricted to practitioners who are subject to appropriate statutory regulation.'*

<https://openair.rgu.ac.uk/handle/10059/176>

⁹ See SI 1031 The Medicines for Human Use (Clinical Trials) Regulations 2004
http://www.legislation.gov.uk/uksi/2004/1031/pdfs/ukxi_20041031_en.pdf.

- Statutory regulation means herbalists can qualify for medical insurance reimbursements from major health insurers and also they will not be subject to VAT on their practices if they are currently VAT registered, as professionals who are statutorily regulated are exempt from VAT on their services.

A statutorily regulated herbal profession - a most valuable public resource

- A statutorily regulated herbal profession will be a valuable resource providing expert herbal guidance on the use of herbal medicines both to other health professionals and the public. Herbal medicine can often be used as a first option in treating many common conditions, sparing the use of more costly conventional drugs and can help to avoid the growing threat of antimicrobial resistance. The NHS budget is subject to mounting pressure and people who choose herbal medicine will increasingly manage their own health care as helping patients to achieve this is integral outcome of herbal treatment. This can mean significant cost savings to the public health system and to the wider economy.

In summary

Taking all this into account, statutory regulation appears by far the best option for the herbal profession to enable it to meet the burgeoning health-care needs of patients throughout the UK. As herbalists practise internal medicine using herbs that in the final analysis are subject to EU medicines law, statutory regulation can assure access to medicines and/or the right to practise in the future. Statutory regulation of UK herbal practitioners is in line with the recent recommendations of WHO calling for integration of traditional medicine systems into the healthcare systems of Member States and to establish systems for the qualification, accreditation or licensing of TM/CAM practitioners.¹⁰

Addendum A

A brief history of statutory regulation of herbalists in the UK

The statutory regulation (SR) of herbal practitioners has been under review for more than 15 years. It was recommended (sections 5.53 & 5.54) by the House of Lords' Select Committee on Science and Technology in its Report on Complementary Medicine (1999-2000) which stated that "*the main criterion for determining the need for statutory regulation is whether the therapy poses a significant risk to the public from its practice*".¹¹ The same conclusion was reached by two Department of Health sponsored Working Groups under the independent Chairmanship of Professor Michael Pittilo. The second of these Reports published in 2008 declared (section 6) that the statutory regulation of herbal medicine practitioners was "*in the public interest*" noting that statutory regulation differs from voluntary regulation because it could "*more effectively assure the standards of those regulated, protecting the public from poor or bad practice, because legal sanctions exist to remove individuals from a register.*"¹²

The reports from these two committees led to two public consultations that demonstrated overwhelming public support for the statutory regulation of herbal practitioners. It is noteworthy that voluntary regulation was rejected as a viable option by all three committees mentioned. They were of one mind; statutory regulation alone could ensure public safety.

Addendum B

¹⁰ WHO traditional medicine strategy: 2014-2023. World Health Organization, 2013. ISBN 978 92 4 150609 0. See also Executive Board and World Health Assembly Resolutions on Traditional Medicine available at www.who.int/medicines/areas/traditional/trm_assembly_doc/en/

¹¹ <http://www.publications.parliament.uk/pa/ld199900/ldselect/ldscitech/123/12301.htm>

¹² Pittilo M. 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. <https://openair.rgu.ac.uk/handle/10059/176>

Legislation pertaining to herbal practice

UK legislation permitting herbal practitioners to prescribe herbal medicines to their patients exempt from a market authorisation (medicines licence) is enacted in the Human Medicines Regulations 2012 (SI 2012/1916) in paragraphs (2), (6), (9) of Regulation 3. This is effectively a transcription of Section 12.1 of the Medicines Act of 1968. This legislation is an exemption from the general requirement for a market authorisation for all medicinal products determined by section 46 of the Human Medicines Regulations 2012.

This is itself also a further exemption from the requirement to hold a marketing authorisation required by Directive 2001/83/EC (chapter 1 Article 6). This exemption is granted because herbal prescriptions made up by the practitioner for patients on an individual basis are neither prepared industrially nor manufactured by a method involving an industrial process and are produced on a small scale. As such these herbal prescriptions are not subject to Article 2.1 of Directive 2001/83/EC that requires medicinal products placed on the market to hold a market authorisation.

It should also be noted that the term herbal practitioner or herbalist does not appear in Human Medicines Regulations 2012 (as was also previously the case for the Medicines Act of 1968). Instead, regulation 241 refers only to the sale or supply of a herbal medicinal product on 'premises occupied by A and from which A can exclude the public' where 'the product is for administration to a person ("B") and A has been requested by or on behalf of B and in B's presence to use A's judgment as to the treatment required.'

With the end of the sell-through period for manufactured herbal medicines that occurred on 30th April 2014, herbal practitioners lost access to all manufactured herbal products supplied by third parties (eg third-party prescription services, pills and capsules) which had hitherto been sanctioned via section 12.2 of the Medicine Act of 1968. This section 12.2 was effectively repealed by the passage into UK law of Directive 2004/24/EC the Traditional Herbal Medicinal Products Directive (THMPD).