

## **STATUTORY REGULATION OF HERBALISTS IN THE UK: REPORT SUMMARY**

The statutory regulation (SR) of herbalists has been an issue debated in herbal world for over ten years. This report covers two separate but intrinsically linked issues: The impact of legislation of the practice of herbal medicine and the impact on herbal medicines. The full report can also be available on this [www.avenaconsultants.co.uk](http://www.avenaconsultants.co.uk) website

### **On statutory Regulation**

Large representative bodies such as The European Herbal and Traditional Practitioners Association (EHTPA) have always been fully behind SR and have also been part of the wider political process to influence herbal policy in the EU and UK. Other groups are against SR and would prefer section 12 of the Medicines Act 1968 and UK common law right to practice to remain intact and unchanged.

Most of the arguments for and against SR are largely academic. They are based on what people believe the outcome will be and how they envisage herbal medicine practice in the UK. Some herbalists would like wider recognition and to be part of a future system of integrated medicine, others would like herbal medicine practice to stay part of common law, a form of medicine people choose to take, with varied forms of training. SR as a concept is primarily based on safeguarding the public. The potential to do harm exists, because anyone can practice as herbalist and give potent herbs like schedule IIIs, but the actual recorded occurrence of harm from practitioners is very low. The issue seems to be one of trust, some trust that herbalists can regulate themselves to do no harm, some would like to see more safeguards against the potential for harm and others believe whether herbalists are statutorily regulated or not, harm can still occur. The results of the latest consultation will also disseminate the views of wide range of groups who are not herbalists and who will also be judging the potential for harm against a backdrop of general scepticism over an solid 'evidence base' for herbal medicine.

Previous government consultations, healthcare related white papers and economic factors have been very influential to the issue of SR. The direction of government focus is now towards ensuring public safety whilst safeguarding the public purse. SR is not at this stage a given outcome; the results of the latest consultation could produce an outcome either way. It seems clear the decision will be made on what is most beneficial to the factors of safety and economics, rather than what is most beneficial to herbalists. The Medicines and Healthcare Regulatory Agency (MHRA) have focused on the issues relevant to herbalists and they have studied the issue of section 12 in more detail than the Department of Health (DH). The DH are focussed on the wider issues of healthcare across the UK, although since 2002, they have set up working groups for herbal medicine and acupuncture, they are not influenced by this one group above another. Since the House of Lords 2001 report, the government was in favour of SR for herbalists and acupuncturists. The original consultation on SR in 2004, actually asked questions about the details of how SR could be organised and by which professional body (at the time a CAM council was proposed) rather than whether it should happen or not. However in 2005 the a general election and the results of the Shipman (Harold) enquiry delayed SR for herbalists while a wider shake up of all healthcare regulation was examined. Various white papers recommended 'streamlining' organisations to ensure better regulation. 'Streamlining' has been a political buzzword in all forms of government policy for the past five years and means tighter organisations, better communication, speedier processes and better budgeting.

In 2006 the Health Professions Council (HPC) which already regulates 14 other healthcare professions emerged as the proposed regulator of herbal medicine and acupuncture. All the working groups have now accepted the HPC as the proposed regulator. The process was going in a relatively smooth direction until the DH commissioned a report from the *working group on extending professional regulation* which stated "Statutory regulation for all is not proportionate, necessary or affordable". Considering the current economic climate this report was unsurprising, however it was quite different from the working group for Herbal Medicine and Acupuncture report which recommended SR without delay. The wording of the latest consultation was highly influenced by

extending professional regulation working group report, with questions about costs, potential risks and alternative forms regulation all related to whether SR for herbalists is 'proportionate, necessary or affordable'. The results will be produced by the DH in the spring, but with the general election due in May and potential change in political party, this issue may delay further.

## **On Herbal Medicines Legislation**

The enforcement date of the EU Traditional Herbal Medicinal Product Directive (THMPD) is April 2011 and this will undoubtedly impact on the herbal market as we know it today. All herbal products whether industrially produced or non industrially produced that are premade will need a Traditional Herbal Registration (THR) Certificate to be sold over the counter and as yet only 39 products have one. The THMPD enforcement is about 16 months away, hence the speed of the movement towards SR for groups that wish to access third party medicines via a 'bona fide unsolicited order' (Article 5 of THMPD). Third party medicines include; Cough syrups, capsules and tincture blends, if these products have THR licences then ordering them will not be a problem. However if they do not, then the manufacturer will require a licence and only healthcare practitioners who are recognised as 'doctors, dentists and supplementary prescribers' (UK amendment 2005 of Medicines Act 1968 to incorporate THMPD) will be able to order unlicensed products. Unlicensed products can be defined as too potent to be sold over the counter so will only be available on prescription. THR certificates are only for herbal products that are considered safe enough to be sold over the counter without the supervision of the above mentioned healthcare professionals.

The term 'authorised healthcare professional' (EU THMP Directive 2004/24/EC) does not exist in UK law, instead professions such as: Doctors, Nurses and Supplementary Prescribers are used to define the people with continuing access to third party medicines (2005 Amendment to Medicines Act 1968 to include THMP, Schedule 1). This is in keeping with EU 'directives' which must be passed into UK law, but by the UK government's choice of form and methods. As a result access to 'unlicensed' third party medicines will be limited to these groups after April 2011. This will impact on practitioners wishing to order products such as pre-made blends i.e. for herbalists without their own dispensary and in particular TCM practitioners who often order blended herbs. It should be noted the EHTPA also represent TCM organisations and the issue of SR is relevant to all these groups' not just western herbalists. In terms of legislation TCM, western herbal medicine and other traditional herbal medicine systems are viewed as one group, so the needs of one have been married to the other.

Section 12 (1) of Medicines Act 1968 will remain intact for 'non-industrially produced' medicines, which includes tinctures, creams and teas made up by practitioners for patients after a one to one or face to face consultation. Herbalists will still be able to order single herbs and ingredients from suppliers. Note Section 12 (2) which deals with OTC remedies will become obsolete after 2011. Access and legislation towards exemptions for 'unlicensed medicines' is relatively vague, so specific details on what exactly will be available are unclear, however popular blends sold in shops like Napiers will be off the shelf unless they have a THR licence or the practitioners are recognised as 'supplementary prescribers' and supply the remedy to a specific patient only.

The MHRA have proposed to consolidate the Medicines Act 1968, because its 40 years worth of amendments and exemptions are difficult even for them to interpret, so it is no longer considered fit for purpose. The consolidation process will take 3 years from 2009 and is likely further impact on herbalists' access to this exemption irrespective of SR. Furthermore almost all respondents on MHRA Section 12 (1) of the Medicine Act consultations have stated that section 12 is too vague and needs to be more robust.

Both arguments for and against statutory regulation have some grounding and this report has attempted to represent a cross range of views. An accurate historical timeline of the facts and legislation has been presented in order to improve legal understanding of this issue. The government have not made a formal decision on statutory regulation and the finer details of EU law and the section 12 of Medicines Act will require further clarification in order to understand the full impact in terms of access to medicines. The situation is evolving and unfixed, however it seems highly likely

that section 12 (1) of the Medicines Act will change in the future. Herbal Medicine has survived for thousands of years and it will undoubtedly survive as long as the plants grow. The main problem seems to be lack of understanding about the profession from groups that have a political influence on how its direction is shaped. Herbalists and users of herbal medicine could work to change these perceptions, however others would argue its best to 'stay under the radar' of politics, although this is probably no longer possible.

The full report on The Statutory Regulation of Herbalists in UK is available from [www.avenaconsultants.co.uk](http://www.avenaconsultants.co.uk)