

Spotlight on herbal medicine

Viv Hinks outlines recent changes to herbal medicine legislation and assesses their impact on aromatherapy practice



Herbal medicine practitioners have previously only been lightly regulated – a situation that many people perceived as unsafe for the general public. However, the statutory regulation of medical herbalists is now imminent, following an announcement in February this year from Secretary of State for Health Andrew Lansley (Lansley 2011).

In his ministerial statement Mr Lansley said: “The issue of whether or not practitioners of acupuncture, herbal medicine and traditional Chinese medicine should be statutorily regulated has been debated since the House of Lords’ Select Committee on Science and Technology’s report in 2000I can now set out how we intend to take forward the regulation of herbal medicine practitioners and traditional Chinese medicines practitioners, specifically with regard to the use of unlicensed herbal medicines within their practice.” (Lansley 2011)

This decision followed several government reports and recommendations including the 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. (Pittilo 2008). This stated that: “The steering group is strongly of the view that the decision to statutorily regulate professions practising herbal medicine and acupuncture is in the public interest” (Point 6, Pittilo 2008)

The confirmation that herbal medicine is to be statutorily regulated has been widely welcomed. Importantly, even if the practice had not become statutorily regulated there would have been difficulties for herbalists due to changes in Section 12 of the Medicines Act 1968.

What’s new

Previously, herbal practitioners were allowed exemptions from the 1968 Act, the relevant section stating:

(1) The restrictions imposed by sections 7 and 8 [Licences and Certificates relating to Medicinal Products] of this

Act do not apply to the sale, supply, manufacture or assembly of any herbal remedy in the course of a business where:

- (a) the remedy is manufactured or assembled on premises of which the person carrying on the business is the occupier and which he is able to close so as to exclude the public, and
- (b) the person carrying on the business sells or supplies the remedy for administration to a particular person after being requested by or on behalf of that person and in that person’s presence to use his own judgment as to the treatment required.

In February this year the Medicines and Healthcare products Regulatory Agency (MHRA) announced: ‘If practitioner regulation is in place for the purposes of creating an Article 5 (1) scheme this also opens the way to reform Section 12 (1) of the Medicines Act 1968. Under Section 12 (1), practitioners may prepare unlicensed herbal medicines on their own premises for use following consultation with individual patients.

It is intended to move to the position that only registered practitioners would be able to operate under Section 12 (1) after regulation of practitioners is in place.’

This change indicates that only statutorily regulated professionals can prepare unlicensed herbal medicines. On reflection, it may be that aromatherapists would have preferred to pursue statutory regulation instead of following the ‘voluntary self regulation’ path.

New marketing rules

There has also been a major change in the way herbal products are sold now that the Traditional Herbal Medicines directive has been fully implemented. This had a seven-year transitional period, allowing herbal medicine manufacturers time to apply for registration.

During this time there was a consultation on reforms of Section 12 (1) of the Medicines Act 1968 in which the IFPA (2007) agreed that regulatory changes were needed, but highlighted the case for a separate category for

aromatherapists. (This did not transpire, largely because the MHRA does not categorise topical essential oil use as necessarily medicinal.)

This transition period ended in April 2011 and the current situation is that herbal medicine manufacturers cannot market herbal medicines without a marketing authorisation or registration as a traditional herbal remedy. This change will help to protect public health, helping to control quality, manufacture and safe ingredients.

How do the changes affect aromatherapists?

You may have heard about these changes and be wondering what it all means for the aromatherapy profession.

There have always been areas of legislation that apply to aromatherapists, in particular cosmetic and medicinal laws but also those regarding trading description and making claims. The recent changes will have limited impact provided that professional aromatherapists continue to be careful in their use, marketing and labelling of products containing essential oils.

Over the past 20 years there have been several occasions where aromatherapists have been concerned about essential oils 'being banned' or 'only available to pharmacists'. Fortunately, these scenarios have not materialised, mainly due to strong, sensible leadership from professional aromatherapy organisations such as the IFPA.

In a recent communication with the MHRA the response was that "the MHRA does not generally regard any product containing essential oils for topical use by aromatherapists as a medicinal product unless medicinal claims are being made. So changes in medicine legislation should not cause changes to aromatherapy practice unless there are claims to treat disease".

It should be noted that the key phrases here are 'topical use' and 'medicinal claims'. Therefore, the best advice we can offer to professional aromatherapists is never to offer oral use of essential oils, and to be extremely careful in any claims, marketing and labelling. If you are at all uncertain check out information sites such as www.mhra.gov.uk and www.a-t-c.org/uk

References

- Lansley A The Secretary of State for Health (2011) Written Ministerial Statement from the Department of Health on Practitioners of Acupuncture, Herbal medicine and Traditional Chinese Medicine
- Pittilo M (Chair of Dept of Health Steering Group) (2008) Report to Ministers on the Statutory Regulation of Practitioners of Acupuncture, Herbal medicine, Traditional Chinese Medicine, and other Traditional Medicine Systems practised in the UK: London HMSO

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News in brief

Aromasticks in cancer care

A recent article in *Complementary therapies in clinical practice* (May; 17(2):116–21) reports on an evaluation of the use of aromasticks (similar in design to the Vicks® Vapour Inhaler®) with cancer patients referred to The Christie NHS Foundation Trust's complementary therapy service. Patients with anxiety, nausea and sleep disturbance all benefitted from using the aromastick.

Full details at www.ncbi.nlm.nih.gov/pubmed/21457903

IFPA CPD centres

Under the IFPA's new CPD Approved Centres scheme, members who have tutor status can now offer IFPA-approved CPD programmes (usually one or two days on a specific topic) and can use the IFPA logo on their awards. See page 36 for details of current centres.

Swiss health system

Five complementary therapies are once again available to Swiss people via their health system. Homeopathy, herbalism, traditional Chinese medicine, 'holistic medicine' (an integrated approach) and neural therapy, which were all available until 2005, will again be reimburseable under Swiss health insurance but the medicines must prove their 'efficacy, cost effectiveness and suitability by 2017.

See www.cam.nhs.uk/news/five-complementary-therapies-supported-again-by-swiss-health-service

Good health show

The Good Health Show will be held at the International Centre, Telford, Shropshire 15–16 October 2011. Show features exhibition stands, seminars, and free taster treatments plus fitness, nutritional and healthy eating advice and guides to mental wellbeing. Visit www.thegoodhealthshow.co.uk

Chinese medicine

You can read articles from the *Chinese Medicine Times* e-journal at www.chinesemedicinetimes.com. Spring edition now available to view.

Research module

The University of Wales Institute's *Introduction to Research for Complementary Therapies* module is available as a stand-alone module. The course aims to support complementary therapy practitioners and health professionals working with complementary therapies to develop skills in reviewing research literature and using a variety of tools to evaluate their practice.

For more information visit www.uwic.ac.uk