Aromatherapy Products and UK Regulations

Current Legislation January 2013

Products supplied by aromatherapists to their clients as part of their clinical practice

Section 12(1) of the UK Medicines Act

It is generally accepted that clinical aromatherapists rely on the provisions of Section 12(1) as the legal basis of their practice.

Section 12(1) is commonly referred to as the 'herbalist exemption' and permits unlicensed remedies to be made up and supplied by a practitioner to meet the needs of an individual patient following a one-to-one consultation.

Following the implementation of the Traditional Herbal Medicinal Products Directive (THMPD) known in the UK as The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 which came into full force on 30 April 2011 practitioners who supply unlicensed herbal remedies have been granted Statutory Regulation, the Healthcare Professions Council have been appointed to set up the statutory register of herbal practitioners and when this is in place it will pave the way for Section 12(1) to be reformed and then only practitioners who are on the register will be allowed in law to supply unlicensed herbal remedies.

Until such time as this process is completed Section 12(1) remains in force and available to aromatherapists, whether aromatherapists can continue to rely on Section 12(1) will depend on the criteria for registration with the Healthcare Professions Council and that will not be published until the consultation scheduled for later this year has taken place and the legislative framework for the reform of Section 12(1) is known. More information can be obtained from:

**Medicines and Healthcare products Regulatory Agency (MHRA)**
http://www.mhra.gov.uk/Howweregulate/Medicines/Herbalmedicines/PlacingaherbalmedicineontheUKmarket/Unlicensedherbalremediesindividualpatients/index.htm

**Department of Health**
http://www.mhra.gov.uk/NewsCentre/CON108789

**Healthcare Professions Council**
http://www.hpc-uk.org/mediaandevents/statements/herbalistandtraditionalchinesemedicinepractitioner
Products supplied by aromatherapists to the general public

There is no single piece of legislation for aromatherapy products and they are controlled by a variety of regulations depending on their purpose and function.

When sold to the general public aromatherapy products typically fall under the following main headings:

1. **Essential oil(s)** packaged as single oil or as a blend of 2 or more essential oils with no other type of ingredient added are typically subject to the General Products Safety Regulation 2005 (GPSR).

   There are specific labelling requirements and they are contained in the regulations, you can download a copy from the following link: [http://www.legislation.gov.uk/uksi/2005/1803/contents/made](http://www.legislation.gov.uk/uksi/2005/1803/contents/made)

   There is an excellent guide produced by the government department responsible for trade and industry BERR available at the following link: [http://www.bis.gov.uk/files/file22713.pdf](http://www.bis.gov.uk/files/file22713.pdf)

2. **Essential oils blended with any other ingredient** for example vegetable oils (described as massage oils) and/or bases like creams, lotions, gels, detergents etc. that meet the definition of a cosmetic are likely to be subject to the Cosmetic Products (Safety) Regulation 2008. **These regulations are much more severe than the General Products Safety Regulations and they can be downloaded from the following link:** [http://www.legislation.gov.uk/uksi/2008/1284/contents/made](http://www.legislation.gov.uk/uksi/2008/1284/contents/made)

   There is an excellent guide to the cosmetics regulations 2008 available at the following link: [http://www.bis.gov.uk/assets/biscore/consumer-issues/docs/guide-to-cpsr.pdf](http://www.bis.gov.uk/assets/biscore/consumer-issues/docs/guide-to-cpsr.pdf)

The cosmetics regulations are changing.


The current Cosmetics Directive 76/768/EEC (as amended) implemented in UK as The Cosmetic Products Safety Regulations 2008 will be repealed on 11 July 2013. Until 11 July 2013 manufacturers can opt to either continue to comply with the Cosmetics Directive (The Cosmetic Products Safety Regulations 2008 in UK) or to comply with the new regulation.

3. Essential oils blended with other ingredients in the form of a spray/diffuser not intended to be applied to the skin e.g. a room spray, wardrobe care etc. is generally classed as a household product subject to the GPSR and/or the CHIP4 regulations now replaced by the Classification, labelling and Packaging Regulation (CLP) see: http://www.hse.gov.uk/chip/index.htm (see ‘The Law’ in menu).

There is also a code of practice operated by AISE for this class of product see: http://www.aise.eu/go.php?pid=44102&topics=17 (scroll down to ‘Documents’, ‘project description’)

4. Products containing essential oils that meet the definition of a medicine by function or by description are controlled by the Medicines Act/Traditional Herbal Medicinal Products Directive (THMPD) as follows: http://www.mhra.gov.uk/Howweregulate/Medicines/Herbalmedicines/index.htm and if they meet the definition of a veterinary product then the Veterinary Medicines Regulations apply as follows: http://www.legislation.gov.uk/uksi/2009/2297/contents/made

5. Candles containing essential oils are likely to be subject to the GPSR, the candle safety labelling code of practice and the European Standard BS EN 15494-2007. A guide to candle safety labelling can be downloaded at: http://www3.hants.gov.uk/tradingstandards/product-safety/candles.htm

6. Essential oils presented on their own or in combination with other ingredients that contain biocidal ingredients or are described as being biocidal, i.e. to kill or repel bacteria, fungi, yeasts, viruses and insects are likely to be considered to be biocides controlled by the Biocides Regulations unless their primary function is as a cosmetic and the biocidal activity/claim is a secondary function in which case they are likely to be subject to the cosmetics regulations, see: http://www.hse.gov.uk/biocides/

7. In addition the UK weights and measures regulations apply when packaging products and is available at the following link: http://www.legislation.gov.uk/uksi/2006/659/contents/made

8. When supplying products to the general public you cannot make medicinal claims (unless the product is licensed under the Medicines Act/THMPD see Guidance note 8 ‘What is a medicine’ published by the MHRA where you can find the sorts of words and phrases MHRA consider to be medicinal and are therefore to be avoided see: http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedalicence/Borderlineproducts/index.htm you can also download a document on how MHRA suggest you construct websites (to avoid making medicinal claims) on the same page.
About Aromatherapy Trade Council (ATC)

ATC is the trade association for the specialist aromatherapy essential oil trade representing the interests of manufacturers and suppliers of essential oils and aromatherapy products.

As Advertising Code Administrators for the specialist industry appointed by MHRA ATC is uniquely placed to offer advice on permitted wording for advertisements, promotional material, labels and websites either on a consultancy basis or as part of a membership package.

Legislation is often complex and frequently confusing and to ensure members keep up to date they benefit from a help desk and regular legislation updates, and for aromatherapists who want to develop their own product range and sell to the public for the first time ATC offers an interim membership package to provide all the help and advice you need to get your project started and completed successfully at a pace to suit you.

For more information about ATC and a list of our members with links to their websites visit our website at: www.a-t-c.org.uk or to enquire about membership or to find out how ATC can help you call Ray Gransby on 01673 844 672 during office hours 10am to 4pm Monday to Friday or email info@a-t-c.org.uk and we will be pleased to help you.

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