THE LAW RELATING TO THE PRACTICE OF AYURVEDA IN UK.

DISCLAIMER

The legal information and opinions provided by the British Ayurvedic Medical Council (BAMC) do not address your individual requirements and are for informational purposes only. They represent the BAMC's current understanding of the law but do not constitute any form of legal advice and should not be relied on or treated as a substitute for advice from a qualified solicitor relevant to your particular circumstances and should not be relied upon by you in making (or refraining from making) any specific decisions.

The law and the interpretation of the law may change with time. Suggestions for correction or update of and improvements to this document will be gratefully received at ask@britishayurvedicmedcouncil.com.

PRACTICE OF AYURVEDA

The practice of Ayurveda in UK is not regulated but the supply of medicines and health products is regulated. UK law permits anyone to give health advice to anyone who asks her/him to do so. Therefore an Ayurveda practitioner can practice in UK without being registered. However the Government prefers health practitioners who are not regulated by law to be members of a self-regulatory body that ensures that its members are adequately trained, insured and informed to practice safely.

Self-regulatory Ayurveda practitioners associations that are members of the BAMC are:
Ayurvedic Medical Association (AMA), www.amauk.info
British Association of Accredited Ayurvedic Practitioners, (BAAAP). https://britayur-practitioners.com/, info@britayur-practitioners.com.
British Marmapuncture Association,

REGULATION OF THE SUPPLY OF MEDICINES AND HEALTH PRODUCTS.

Medicines

Supply of medicinal products is governed by Human Medicines Regulations 2012 which sets out a comprehensive regime for the authorisation of medicinal products; for the manufacture, import, distribution, sale and supply of those products; for their labelling and advertising; and for pharmacovigilance. In addition to the authorisation process for medicines (Part 5) there are procedures for registration of Traditional Herbal Medicinal Products (Part 7).

The definition of medicinal products in these regulations has two arms relating to the way they are presented and/or by their function:

(a) any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or

(b) any substance or combination of substances that may be used by or administered to human beings with a view to—

(i) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or

(ii) making a medical diagnosis.

Since almost everything can modify physiological function by exerting a metabolic action (e.g. a glass of water) the function arm of this definition is deeply problematic.

Traditional Herbal Medicines Registrations (THRs)

Traditional Herbal Medicines can be registered by a regime that is less demanding than the regime for other medicines. This requires proof of quality, plausible efficacy, and a record of traditional use of 30 years of which 15 years are in the EU or another place where their use has been subject to some pharmacovigilance regime.

THRs can only apply to products for oral or external use and/or inhalation and for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment. The registration process can take at least 18 months and cost very approximately £200,000 per ingredient (e.g. a product with three ingredients about £600k).

Difficulties with the THR are:

- The proof of 30/15 years traditional use needs to apply to the same or a corresponding formula – that is one having the same active ingredients, the same or similar intended purpose, equivalent strength and posology and the same or similar route of administration. However it can also apply to products where the number or quantity of ingredients has been reduced during that period. However history of use of formulae where an ingredient has been substituted by a corresponding ingredients does not contribute to the history required for the registration of the original formula.
- Vitamins and minerals can be present but only in an ancillary role. In practice other non-plant ingredients may also be permitted.

Herbal Practitioner Medicines.

The Human Medicines Regulations 2012 prohibits anyone from manufacturing, assembling, importing or possessing a medicine without a licence except for administration to himself or herself or to any other person who is a member of that person's household. However Regulation 3.2 and 3.6 exempt from this restriction the manufacture or assembly of a herbal medicinal product by a 'herbal practitioner', including a Ayurveda practitioner, in the context of a one-to-one consultation. But note that this exemption does not allow herbal practitioners to supply herbal medicines purchased from anyone else and the manufacture or assembly of a herbal medicinal product by a 'herbal practitioner may not be done (a) on a large scale; or (b) by an industrial process.

Note also that the term 'herbal practitioner' is not defined in the legislation therefore a person with even slight knowledge of herbal medicines can claim to be a herbal practitioner. and that the use of certain ingredients is restricted or banned – see MHRA website .

REGULATION OF FOODS.

Foods including food supplements can be supplied for the maintenance and promotion of health without any registration or licence provided they are safe for use as directed. There is a range of legislation covering food products,– see Food Standards Agency website and particularly the Food Information Regulations 2014 (FIR) as amended.. The FIR makes detailed rules on labelling of ingredients, pack size, potential allergens, nano materials, legibility of labels, nutrition declarations and best before dating.

There are also laws setting limits to certain contaminants in foods and the use of additives – see FSA guidance.

Nutrition and Health Claims Regulations 1924/2006 (NHCR) applies to what can be said about the benefits of eating a food that is placed on the open market. It does not apply to what a practitioner can say to a client.

Food ingredients that were not in use to a 'significant degree' before May 1997 are classified as Novel Foods and require an assessment of their safety before they are used. – see FSA guidance.

REGULATION OF COSMETICS

A cosmetic product is defined in detail as ***any substance or mixture intended to be placed in contact with the external parts of the human body*** *(epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.* Thus Ayurvedic massage oils are not cosmetics.

Cosmetic products can be supplied without a license but must be registered under the terms of the Cosmetic Products Regulation (1223/2009) as amended by Schedule 34 of the Product Safety and Metrology SI - see CTPA guidance . There is extensive regulation of cosmetic ingredients especially man-made chemicals.

REGULATION OF GENERAL PRODUCTS

If a product does not fall within any specific product category (medicine, food, cosmetic etc) then it is a general product. Aroma oils and external products which are not cosmetics are general products. Suppliers must ensure these are safe when used as directed.

CONCLUSION

It is possible to practice Ayurveda legally in the UK but there are obstacles. The greatest obstacles relate to the supply of medicines where the definition of what is a medicine makes little sense in the context of Ayurveda. However since the role of Ayurveda as described by Charak Sutrasthanam 30/26 is *Swasthasya swasthya rakshanam aturasya vikara prashamanam*, putting maintenance of health before cure of disease, Ayurveda can still do a lot in UK without involving 'medicinal products' as defined in UK law.

If a person's health can be improved by an Ayurvedic formula which cannot legally be supplied as a medicinal product this may not mean that it cannot legally be supplied under another legal category – food supplement, cosmetic or general product.