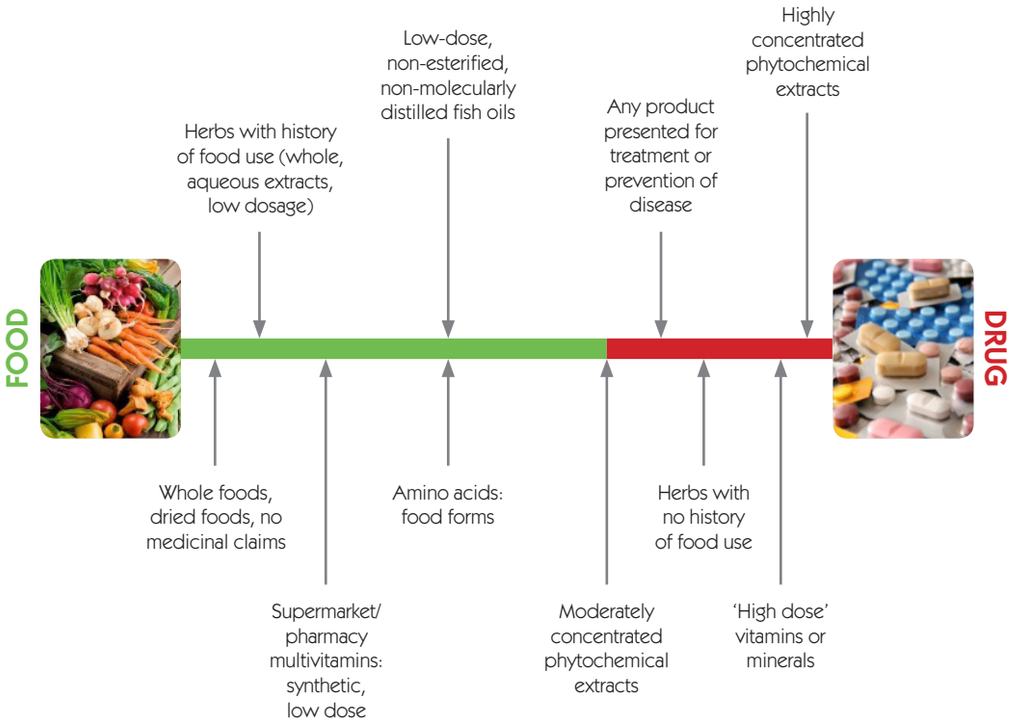
Treading the fine line of the food/drug borderline



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Practitioners

"Building your practice while negotiating the EU regulatory minefield"

Relevant legislation
Human Medicinal Products Directive (HMPD; Directive 2001/83/EC, as amended); Food Supplements Directive (FSD; Directive 2002/46/EC, as amended); Nutrition and Health Claims Regulation (NHCR; Regulation 1924/2006, as amended)

An uncertain future for practitioners

The use of natural products to manage human health is as old as humanity itself. Humans have learned through experience, trial and error and, more recently, through clinical and scientific investigation, that natural products can have profound influences on health.

We are now entering a phase in which the greatest burden on healthcare is caused by a handful of largely preventable chronic diseases that are mainly the result of inappropriate diets and lifestyles, and excessive stress. Complementary and alternative medicine (CAM), integrative medicine and traditional systems of medicine offer multi-faceted approaches to the prevention and management of these diseases that cannot be matched by the predominantly pharmacological approach used in mainstream medicine. Yet, the practice of CAM modalities and the use of natural substances is deeply threatened by the absence of specific regulatory regimes for practitioners, and the presence of inappropriate European Union (EU) regulatory regimes affecting natural products.

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Use of natural products by CAM practitioners

Only in the UK is there a unique exemption for herbalists allowing them to use unregistered medicines following one-to-one consultations. Elsewhere in the EU, non-medically trained CAM practitioners are unable to prescribe or recommend natural products that are different to those available to lay members of the public. This is simply not logical or appropriate given the burden that appropriately regulated CAM practitioners could lift from national healthcare systems. Medically trained practitioners, by contrast, are able to benefit from an exemption in European medicinal law. This allows them to use unregistered medicines, "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" (Article 5.1, HMPD).

Three important challenges facing the use of natural products by non-medically trained practitioners are:

Ingredients: Restrictions on the availability of natural products as food supplements. The development of positive lists, and the increased classification of ingredients as unregistered medicines or unauthorised novel food ingredients, is greatly narrowing the scope of products available legitimately as food supplements. The effects are most profound on particular botanical ingredients and other substances that are not typically consumed as a normal part of the diet

Dosages: The EU will be harmonising maximum doses of vitamin and mineral food supplements (as per Article 5, FSD), and this will limit the availability of higher-dose products. High doses of botanicals and other nutritional substances are increasingly being regarded by regulators as medicinal

Health claims: The EU's NHCR greatly limits the ability of practitioners to communicate in person, or via other media including marketing material and websites, about the health benefits of food and food ingredients.

Three important challenges facing the use of natural products by non-medically trained practitioners concern ingredients, dosages and health claims

When are practitioners most exposed?

Questionnaire and consultation: You are at risk of making medical diagnoses

Oral treatment recommendations/protocols: You are at risk of making medicinal claims and unauthorised health claims

Written recommendations / protocols: You are at risk of making medicinal claims, using unregistered medicines or unauthorised novel foods

Promotional materials and websites: You are at risk of making non-authorised health claims and medicinal claims

Bottom-line advice to practitioners

- Don't offer any diagnoses (except to yourself!)
- Don't associate commercial products with modifying, correcting or restoring health, or any pharmacological action
- Check the legality of products you recommend
- Get yourself familiar with the NHCR (see 'Health Claims in Europe' leaflet) when considering claims about the beneficial effects of commercial products
- Keep commercial product recommendations separate from medical history and protocol (which can be generic)
- Avoid any medicinal claims and unauthorised health claims on any websites, promotional materials, etc.
- Stay informed and engaged with the actions ANH-Intl takes to help practitioners, and share this information with colleagues and clients
- Keep us informed about any regulatory challenges you are facing so we can respond accordingly
- Stay abreast of any national advertising codes that affect claims about the services you offer, and ensure those claims can be substantiated adequately
- Encourage your practitioner association to become an ANH-Intl Collaborating Practitioner Organisation – if it isn't already!
- Sign up to our Practitioners Newsletter (email yvonne@anhinternational.org) and our weekly eAlerts from ANH Europe (see homepage, www.anh-europe.org)
- Please support us financially and in other way you can, to enable us to work collaboratively to continue to make a difference to the future of natural healthcare.

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