

ANH International Summary: Key challenges to natural methods of healthcare in Europe



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INTRODUCTION

This report provides a summary of some of the key regulatory challenges facing certain natural modalities of healthcare in Europe. It also highlights relevant areas of ANH-Intl's activity, as one of the leading international non-profit NGOs working to safeguard natural and sustainable approaches to healthcare worldwide.

BACKGROUND

Two important preliminary points of note are:

Firstly, the primary regulatory threats are to nutritional, phytonutrient/herbal and homoeopathic medicine, i.e. those modalities based on oral ingestion. Such orally-ingested products compete most directly with licensed pharmaceutical drugs and are used by over 50% of the population either in place of or as an adjunct to conventional forms of medicine.

Secondly, nutrition as a healthcare modality is often ignored by complementary and alternative medicine (CAM) interests. The practice of nutritional medicine (sometimes also referred to as nutritional therapy or functional medicine), which takes a much broader view of the use of nutritional factors in healthcare than the nutrition or dietetics practised in a conventional sense, is now heavily threatened by regulation. However, it provides one of the most fundamental elements to any natural and sustainable approach to healthcare. The background to this is set out in an Alliance for Natural Health White Paper entitled '*Sustainable Healthcare: Working Towards a Paradigm Shift*'.¹

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THE KEY THREATS TO ORALLY-INGESTED NATURAL (OR 'ALTERNATIVE') HEALTHCARE PRODUCTS

1. Nutritionally-based healthcare modalities

1.1 Key challenges

Nutrition can loosely be divided into two main areas: the use of macronutrients (carbohydrates, proteins and fats) and micronutrients (vitamins, minerals, amino acids, essential fatty acids, plant extracts, etc.).

1.1.1 Making health claims about foods and food ingredients

In terms of regulatory threats, the ability to communicate within a commercial context about the health benefits of foods and food ingredients is massively threatened by the EU's **Nutrition and Health Claims Regulation** (No 1924/2006). Its first (relatively minor) provisions came into force as of July 2007. Its most far-reaching measures have yet to be enacted or enforced. The regulation affects any claim as to the nutritional content or health benefit of any food or food ingredient (including all nutritional and botanical supplements) sold in the UK, as well as all other 26 EU member states. In essence, it uses Napoleonic law to prevent any manufacturer, retailer or practitioner (i.e., 'food business operator' under the terms of the regulation) making any claim about the health benefit of a food or food ingredient, unless the claim is pre-approved by the Parma-based European Food Safety Authority (EFSA). Owing to the almost impossible standards, established by the regulation for proving causal relationships, the vast majority of claims evaluated to-date by EFSA, especially those that relate to botanical ingredients, have been negative. This means no claims of any sort will be able to be made for such foods or ingredients once the regulation comes fully into force.

The key challenges posed by the regulation are set out in an ANH Briefing Paper on the subject available on our website.ⁱⁱ The regulation affects claims made in any medium, whether verbal, written, pictorial, video etc.

The EFSA's evaluations have yet to be completed hence the continued allowance of claims previously accepted under national laws (one of the transition measures set out in the regulation). Full enforcement of the regulation will occur once the EFSA's evaluations are complete, currently estimated to be end-2011.

The implications of this short-sightedness on the part of EU authorities are dramatic given the effect on the ability for people, companies and practitioners to communicate openly about the benefits of foods and nutritional products.

The impact on freedom of speech with regard to communications about food is almost certainly unprecedented anywhere in the world. Anthropologically, the implications of this are profound given that most knowledge about the benefits (and

harmfulness) of foods has been handed down from one generation to the next based on human experience. The regulation also works counter to any moves towards preventative healthcare approaches based on diet and lifestyle, recognised even by the World Health Organisation as the most important contributors to reducing the burden of the major chronic diseases.ⁱⁱⁱ

1.1.2 Vitamin and mineral food supplements

The EU **Food Supplements Directive** (2002/46/EC)^{iv} came into force in 2002 and regulates EU-wide all vitamins and minerals delivered in dose form. It controls which vitamin and mineral forms can be used (as of January 2010) and contains provisions that aim to regulate the maximum (and minimum) daily amounts of vitamins and minerals sold as food supplements. Additionally, the directive contains provisions to control the quality and labelling of food supplements.

Although the European Commission has for the time being stated it does not intend to apply this type of regulation to other groups of nutrients such as plant extracts, essential fatty acids and amino acids, the possibility exists.

As far as vitamin and mineral forms are concerned, several hundred that were used prior to 2010 have been disallowed owing to the difficulties (especially the prohibitive cost) of their meeting pre-approval by European authorities, including characterisation and safety evaluation. This includes many mineral amino acid chelates, the form of minerals generally preferred by nutritional therapists, as well as all forms of vanadium (a key mineral to help support blood-glucose management) and silver products (the widely used 'natural antibiotic').

Methods to determine maximum levels for food supplements are presently being developed by European authorities. In general terms, the methods so far being considered are seriously flawed scientifically, this being the subject of two peer-reviewed scientific papers in the official journal of the British and German Toxicological Societies, *Toxicology*. If the methods of determining maximum levels are not altered, it is highly likely that allowed dosages will be so low that any therapeutic usage of vitamins and minerals will become impossible.^v

1.2 ANH-Intl's response

With respect to the Nutrition and Health Claims Regulation, we are hopeful that major food industry associations or interests will challenge its many problems, probably via judicial review. Unusually, this is one regulatory issue over which almost the entire, broad and diverse cross-section of food and supplement industry interests are united. Given our limited resources, we will continue to watch closely how the major interests respond and will only take action if a) others fail to act and b) if we have the necessary resources to act.

Some of the key strategies implemented by the ANH-Intl to-date with regard to the Food Supplements Directive are:

- a) Judicial review undertaken in the High Court in London, which was in turn referred to the European Court of Justice (2003-5). The case (*Alliance for Natural Health and others v UK*; C-154/04) resulted in important clarification, reduction of legal uncertainty and exclusion from the directive of natural sources of vitamins and minerals that would otherwise have been banned owing to the difficulty and cost inherent in characterising their constituents and proving their safety according to the required standards.
- b) Official petition in the European Parliament, which questions the scientific methods of risk analysis being used by European Authorities. The petition is still 'live' and its content will be discussed shortly by the key European Parliamentary Committee dealing with issues of consumer safety.
- c) Critical evaluation of risk analysis methodologies being used by European authorities for the proposed statutory limitation of vitamin and mineral doses EU-wide. These findings have been accepted for publication in the journal *Toxicology*.^{vi}
- d) Extensive lobbying and advocacy in the European Parliament, European Commission and EFSA.

2. Botanically-based healthcare modalities

The implications of a range of European laws on the ability to use plant-based nutrients for healthcare purposes is probably the area of future legislative impact that is least understood by major segments of the food, supplement and herbal medicine sector. Part of the reason for this is the sheer number of different pieces of legislation affecting botanicals, both EU-wide and nationally. These include the EU **Traditional Herbal Medicinal Products Directive** (1924/2004) (THMPD), and the **Novel Food Regulation** (No 258/97). Additionally, risk management guidance has been issued by the EFSA in an attempt to bring different national approaches into line.

2.1 Key challenges

The vast majority of products sold in the UK up until now that are based on concentrated botanical sources have been sold as botanical food supplements. This includes the diverse range of products originating from two of the oldest surviving traditional healthcare systems, those of China and India (i.e., traditional Chinese medicine and Ayurveda) respectively. Certain products dispensed by western herbalists have benefited from the exemption under Section 12(1) of the UK Medicines Act that allows herbal medicines to be prescribed by herbalists in one to one consultations. The future of this exemption has been up in the air for some time,

and, especially given the delay in imposing a system of statutory regulation for practitioners of herbal medicine, it could well be lost.

The THMPD was developed as a simplified licensing system for traditional medicines, including those of non-European origin, such as TCM and Ayurveda. Ironically, after the near-exhaustion of the 7-year transition phase of the directive, not a single TCM or Ayurvedic product has so far been licensed successfully. This is because there are prohibitive eligibility or technical problems for these non-European herbal medicines.^{vii}

The end of the transition phase of the THMPD on 31st March 2011, effectively marks an unstated transition in regimes for the thousands of botanically-based food supplement products that have been sold safely in the UK (and with great benefit to consumers) for decades. Products to be affected will include those based on plants that are not normally consumed as conventional foods or have had a history of medicinal, rather than food, use.

The effects of these regulatory changes on the practice of traditional herbal medicine in the UK will be catastrophic unless regulatory reform is achieved in the coming year or two. We have been working with Chinese and Indian interests in this regard.

The production of medicinal plants has represented a significant livelihood for millions of people in different parts of the world. The growing interest in plant-based medicine in the western world in recent decades has led to a growth in the cultivation and wild-crafting of such herbs. Europe, with its stronghold of 500 million citizens, represents one of the world's single biggest markets. Its constriction caused by restrictive regulation will have knock-on consequences on herbal producers in developing countries. The impact on the livelihoods of these producers could encourage a return to environmentally damaging practices such as slash and burn agriculture and deforestation.

2.2 *ANH-Intl's response*

We are working on a wide range of strategies with the purpose of reducing the negative regulatory impact on botanically-based products. These are summarised below:

- a) We are preparing a judicial review of the THMPD, which we aim to file in the High Court in London before the end of 2010. The case is being supported by a very wide range of herbal medicine interests, particularly from the TCM and Ayurveda sectors. The purpose of the case is to keep open the botanical food supplement regime, while simultaneously applying pressure for reform of the THMPD itself to allow easier registration of products while in no way compromising consumer safety. We acknowledge that there have been limited cases of concern over misidentification and contamination of Chinese

and Indian herbal products and we support regulatory systems that deal with such problems.

- b) We are facilitating communications with the Chinese and Indian interests, including government departments, with regard to the practical steps and actions to be taken to ensure that European legislation is prevented from discriminating against some of the oldest traditional medicinal cultures in the world.
- c) We are supporting the efforts of the European-based Benefyt Foundation in trying to develop a strand of European medicinal law that applies specifically to herbal practitioners.
- d) We are working closely with European Members of Parliament that share our concerns, and who are interested in seeing major reform of the poorly construed European laws affecting herbal products.

3. Homoeopathy

3.1 Key challenges

While homoeopathy is greatly threatened, particularly in terms of its acceptance as a plausible modality by mainstream medicine and the National Health Service in the UK, the main threats are not currently regulatory in nature. They are primarily down to differences in interpretation of the evidence. Along with the key scientific issues facing homoeopathy: it is noteworthy that despite a powerful balance of evidence from systematic reviews and meta-analyses showing clear benefits overall, for a wide range of indications, there is still strong antagonism towards the modality.

3.2 ANH-Intl's response

We believe this is best countered by continuing to present the full evidence-base, particularly from human trials, as well as by developing better scientific methods for the evaluation of clinical and experiential evidence. These are issues about which we have presented at the two 'Scientific Research in Homeopathy' conferences convened by the Complementary Medical Association in London in 2008 and 2010 respectively. Dr Robert Verkerk wrote an article (entitled "*Professor Ernst: master trickster or evidence-based medicine?*") in 2007, which explains why Prof Ernst (of Peninsula Medical School, Exeter, UK) has consistently been unable to make positive findings for homoeopathy, which gives useful background.^{viii}

Together with doctors and scientists around the world, as part of our newly established international scientific and medical collaboration, we are presently working on developing scientifically-based methodologies that can objectively and quantitatively evaluate clinical experience by the patient. We see such methods as

being of vital importance to counter the misleading results sometimes generated by randomised clinical trials.

4. CONCLUSIONS

The sheer extent and complexity of European laws affecting natural healthcare means that few European citizens are fully cognisant of the future impacts of the laws. Even many major, established industry players are less than fully informed. Many of the laws are already in place, yet their key provisions have yet to come into force. These laws overrule many that have previously existed nationally, so they effectively spell an end of sovereignty in the field of natural healthcare. This process of delegation from national to European law is further cemented by the Lisbon Treaty that hands all areas of law that relate to consumer protection to centralised control in Brussels.

The European model for food regulation is fast becoming the template for global regulation, as seen by the development of international recommendations, guidelines and standards under Codex Alimentarius.

There is a growing body of evidence that major food, drug and biotechnology corporations are the primary drivers of such regulation. It is becoming increasingly apparent that natural, sustainable and biologically-compatible healthcare approaches, that favour disease prevention, are not supported by these industries given that they would negatively impact their profits.

In our view, the sheer burden of chronic and infectious diseases on the global population means we need to strive to develop an alternative paradigm for human healthcare. We advocate that such a paradigm must be based on the principles of sustainability and intrinsic biological compatibility.

For further information, please refer to:

www.anhinternational.org and www.anh-europe.org.

REFERENCES

ⁱ ANH White Paper on sustainable healthcare: http://www.anh-europe.org/files/100617-SustainableHealthcare_White-Paper.pdf

ⁱⁱ ANH Briefing Paper on EU Nutrition and Health Claims Regulation: http://www.anhcampaign.org/files/091208_ANH-Briefing-Paper_NHCR.pdf

ⁱⁱⁱ WHO Global Strategy on Diet, Physical Activity and Health: <http://www.who.int/dietphysicalactivity/en>.

iv ANH Briefing Paper on EU Food Supplements Directive:

http://www.anhcampaign.org/files/080630_ANH-Briefing-Paper_FSD-general.pdf

v ANH Briefing Paper on Maximum Permitted Levels (MPLs) of vitamin and mineral food supplements: http://www.anhcampaign.org/files/100218_ANH_Briefing_Paper_FSD_MPLs.pdf

vi PubMed abstracts of two *Toxicology* papers by ANH Science Unit critiquing EU risk analysis methodologies, currently 'in press':

www.ncbi.nlm.nih.gov/pubmed/20035821

www.ncbi.nlm.nih.gov/pubmed/20188138

[full PDFs of these papers are available on request]

vii ANH Briefing Paper on the Traditional Herbal Medicinal Products Directive:

http://www.anhcampaign.org/files/080630_ANH-Briefing_Paper_THMPD.pdf

viii ANH article on the limitations of Professor Ernst's methodologies for the evaluation of evidence-based medicine: http://anh-europe.org/files/071115-Edzard-Ernst-exposee_final.pdf