

ANH INTERNATIONAL: PRACTITIONERS' NEWSLETTER

JANUARY to JULY 2011

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EUROPE

ANH-Intl/ EBF busy preparing for legal challenge as EU herb ban begins

Practitioners lose access to many herbal products

Sunday 1st May, 2011, was 'zero hour' for manufactured herbal medicinal products in the European Union (EU). On that date, the Traditional Herbal Medicinal Products Directive (THMPD) came [fully into force](#), and any herbal medicines without a so-called traditional use registration (TUR) became illegal to manufacture.

Practitioners who use manufactured herbal medicines, outside the UK where the Medicines and Healthcare products Regulatory Agency (MHRA) is allowing a 'sell-through' period of unlicensed herbal medicines, are now unable to access hundreds of safe and effective herbal medicinal products. Practitioners with patients who used to rely on products that are, or will soon become, unavailable could see them turning to the 'direct-to-consumer' route of buying their products from outside the EU, via mail order or the Internet. However, there can be no guarantee that customs services will not stop the import of unlicensed herbal products at the border and there is always the issue of quality. It's therefore advisable for practitioners to, if possible, discuss potential purchases with patients beforehand.

Great traditions under threat from narrow THMPD scheme

Why are so many products being lost? For a start, relatively few licenses have actually been [obtained](#), representing a very small number of herbal species. Furthermore, the THMPD's technical requirements effectively [lock out](#) the great traditions of [Ayurveda](#) and traditional Chinese medicine, along with Unani, Tibetan, Amazonian and African traditions, Japanese Kampo and others.

All herbal medicinal traditions are affected in some way, including Western, and retailers are beginning to [feel the pinch](#). However, practitioners of Ayurveda and TCM, especially, will be hard hit by the THMPD because of their increased reliance on manufactured products. Now is the time for herbal practitioners to lobby their professional organisations to get involved in campaigns to reform the THMPD, such as the ANH-Intl/European Benefyt Foundation (EBF) legal challenge – and, of course, to [get involved](#) on an individual basis!

The THMPD: a fundamentally flawed Directive

All of ANH-Intl's concerns about THMPD are detailed in an [open letter to Commissioner Dalli](#), written by Dr Robert Verkerk. Dr Verkerk's letter followed an open forum in the European Parliament that saw the European Commission and the European Medicines Agency take questions from many [concerned parties](#), including Dr Verkerk, who was one of four invited experts. This meeting can be viewed on an [archived video stream](#). Our concerns are also summarised in a set of [Frequently Answered Questions](#).

THMPD legal challenge imminent

As we have made clear for some time, ANH-Intl and our partners at the European Benefyt Foundation (EBF) intend to [initiate judicial review proceedings](#) over the THMPD. The

complexity of a case that spans the EU's 27 Member States, and the availability of new evidence post-May 2011, has forced a [delay](#) in the initiation of our challenge as compared with our original proposed timeline. But practitioners can rest assured that the legal challenge will be brought as soon as possible – and your support is crucial to our success!

Practitioners respond to herb challenge appeal

While on the topic of our legal challenge, ANH-Intl/ EBF would like to thank all the practitioners and practitioner organisations who have so generously [donated funds](#) for the first stage of their EU herb law challenge. Those that donated over £500 are listed on our [THMPD support base](#).

This money will be used for the first stage of our legal challenge: the Judicial Review in the Royal Courts of justice in London. The initial target amount of £90,000 was successfully achieved. ANH-Intl/ EBF will resume fundraising for the legal action once we achieve the anticipated referral of our case to the European Court of Justice. But please remember that we are a not-for-profit organisation funded only on donations, so your ongoing support is necessary if you would like to see our work continuing. Please consider setting up a [regular monthly donation](#) of £5/€5/\$5 and suggest your patients might like to consider something similar. A little from a lot of people makes a huge amount of difference to us!

Lessons from the UK: Relearning the 'rules of the game', natural healthcare integration and other news

Self-protection for practitioners

The difficulties for natural healthcare practitioners posed by the EU regulatory juggernaut are compounded by the anti-natural healthcare 'skeptical' movement, which is growing across the EU. For example, it is now actively [attacking UK practitioners](#), including [herbalists](#). In this climate, ANH-Intl believes it is vital for practitioners to do all they can to protect themselves. The importance of getting up to speed with the 'juggernaut' of EU legislation and other national rules and codes cannot be over-emphasised.

To help practitioners negotiate the legislative minefield in which they operate, ANH-Intl ran its first [educational event](#) in May 2011 for practitioners who use nutritional and herbal interventions. Held at the Royal Society of Medicine, the extremely well-received event was delivered by Dr Rob Verkerk and Meleni Aldridge, and superbly organised by [Health4Life/Inside-Out Nutrition](#). "*The rules of the game have now changed with the introduction of all the EU legislation,*" said Ms Aldridge at the event. "*We now need to know how to play smart within and around them.*"

Integration: the future of natural healthcare?

Integration of natural healthcare modalities into national health systems is increasingly on the agenda, especially in our current 'age of austerity'. How to manage this integration is an important developing discussion, and one which practitioners must be aware of and

involved in. In the UK, a recent [College of Medicine symposium](#) revealed that the College foresees herbal medicine becoming available on the UK National Health Service (NHS). Many indications from the symposium were that a 'watered down' version of herbal medicine, courtesy of the EU, will make it into the NHS.

Herbalism to be a state-regulated profession in the UK

[Analysis](#) of the herbal products granted a THR reveals that the vast majority are alcohol or acetone extracts, as opposed to whole-herb products, which are then stabilised in a pharmaceutical base. The obvious option, then, for EU citizens wishing to obtain whole herbs or products based on whole herbs is to consult an herbalist. In February 2011, the UK government appeared to support the country's herbalists by announcing that they will receive [statutory regulation](#) (SR). This effectively means they will be viewed as "authorised healthcare professionals" in the UK under EU medicines law, allowing them to prescribe unlicensed herbal medicines to meet the special needs of their patient.

UK herbalists must work toward good legislation

However, things are not so simple, especially for the [UK press](#)! Depending on one's interpretation of [UK government and MHRA statements](#), herbalists may lose their long-held right to make up prescriptions on their consulting premises. Herbal practitioners' organisations need to keep a very careful eye on that one, as the real battle now begins to shape the eventual SR legislation in a positive manner.

EU position on supplements supported by propaganda

Along similar lines, practitioners using nutritional supplements should be aware that national health systems may follow the UK NHS' lead in [adopting the EU's restrictive line](#) on food supplements. The NHS paid consultants to write a deceptive report based on flawed science to make the EU-mandated position appear 'evidence-based': a pure propaganda technique to which practitioners across the EU must be alert.

Natural healthcare and chronic disease

Two new studies showed clearly that solutions for chronic disease are urgently needed, but remain as distant as ever in mainstream medicine. A study of over 13,000 people over the age of 65 showed that [polypharmacy](#) significantly increases the risk of death, while a Lancet study demonstrated that the UK's cancer treatment strategy simply [isn't working](#) – and similar strategies are in place in most Western countries.

Of course, you and we both know where the answers lie – natural healthcare!

Development of [biocompatible and sustainable healthcare](#) is one of ANH-Intl's core campaigns. An [article](#) written by Michael Ash BSc DO ND Dip ION, of Nutri-Link Ltd, explains why natural approaches to healthcare, and especially so-called 'integrative' medicine, may be the way forward in this era of chronic disease.

Other Europe News

The following may also be of interest to European practitioners:

[European patient groups call for mandatory vaccine surveillance systems](#)

[European Parliament refuses to approve European Medicines Agency accounts](#)

[MEP concerns mount over regulatory threats to natural healthcare](#)

[Health Claims: European Food Safety Authority \(EFSA\) carries on regardless](#)

[EFSA rules that drinking water does not prevent dehydration](#)

USA

FDA's NDI guidelines: threat to innovation and based on controversial EU 'Novel Food' Regulation template

New Dietary Ingredient guidance threatens natural products

US practitioners who rely on diverse natural ingredients and new supplements in their practices need to be aware of a [serious threat](#) to these natural products. The threat arises from the Food and Drug Administration (FDA) draft guidance for complying with the 'New Dietary Ingredient' (NDI) notification protocols of the Dietary Supplement Health and Education Act (DSHEA).

DSHEA, which was passed in 1994, has always contained a requirement for notification of NDIs by supplement manufacturers. However, until July 1 this year, very little guidance had been given by the government about what exactly an NDI is, and how to go about 'notification'. The Government had been ignoring or enforcing the notification requirement as it saw fit.

It is important to realise that this new 'guidance' could now be used to prevent the sale of any 'new' product actually developed after 1994, as well as any future new and innovative products.

EU Novel Foods Regulation reaches the USA

This situation is uncannily similar to the threat posed by the European Union's Novel Foods Regulation. In Europe, natural products are forced off the market by being declared "unlicensed drugs", or by being classified as unauthorized "novel foods". This regulator's tool, so important in Europe, is about to be unleashed on an unsuspecting American public also. Dr Robert Verkerk has explained this in a [special report](#).

NDI guidance a gift for pharma companies

More worrying still, while the supplement manufacturer is busy trying to meet the onerous NDI (supplement) notification standards in order to receive FDA approval, a drug company can, in the meantime, file an Investigational New Drug (IND) application for a natural substance, which will then [prevent availability](#) of the substance in its natural form altogether.

All practitioners are urged to contact the FDA immediately and voice their strong [opposition](#) to the New Dietary Ingredient draft guidance!

Durbin Bill: another attempt to limit access to dietary supplements?

Melatonin brownies controversy inspires Durbin anti-supplements bill

Another bill that proposes to modify the procedures set forth by DSHEA, is Senator Durbin's "[Dietary Supplement Labeling Act](#)". The Durbin bill was apparently created in response to the recent "Lazy Cakes" brownie controversy, where a renegade food company sold brownies containing melatonin. But it appears to be yet another attempt to limit access to dietary supplements!

FDA further consolidates its power over dietary ingredients

The proposed law enables the FDA and the Institute of Medicine (IOM) to decide what levels and combinations of dietary ingredients are considered safe and what aren't, with mandatory warnings put on labels for any ingredient on this list. Practitioners will have little faith in the guidance of these organizations, with the FDA's profound bias against supplements, and the poor science revealed in the IOM's recent vitamin D report.

Red tape will stifle innovation

DSHEA already requires ingredients lists and FDA pre-approved health claims, and that supplements must be manufactured according to Good Manufacturing Practice standards. The unnecessary and burdensome red tape, paperwork, and labeling requirements contained in the Durbin bill will make it more expensive to manufacture supplements, thereby dampening innovation.

ANH-Intl urges US practitioners to help in defeating this bill also. [Please contact your senators.](#)

No place for legitimate science behind a food supplement's effectiveness

FDA: health claim + food supplement = drug

Practitioners are incredulous when they learn of the regulator's view that making a health claim about a food supplement instantly turns it into a drug. If such a supplement is associated with a health claim, it must then go through the FDA drug approval process or it cannot be sold. Alternatively, it can be sold, but no-one may tell anyone about its health benefits! Read ANH-USA's [newsletter article](#) about this ridiculous state of affairs.

Support the Free Speech About Science Act

There must be a system that allows consumers to access credible scientific data, through legislation like the Free Speech About Science (FSAS) Act, HR 1364.

US Practitioners are urged to read ANH-USA's [Action Alert](#) , and to ask Congress to support the Free Speech about Science Act!

Pressure from Texas Medical Association threatens chiropractors with practice restrictions

Texan chiropractors face loss of integrative approach

Under pressure from the Texas Medical Association, the Texas Board of Chiropractic Examiners (TBCE) wants to greatly [limit the scope](#) of chiropractic practice in Texas. This would result in a loss of the integrated approach, as chiropractors will be forced to focus narrowly on the spine.

While integrated medicine in Texas receives a boost

In the meantime, also in Texas, it seems a bill has been introduced (HB 2455) to create the [Texas Board of Integrative Medicine](#) . This is very heartening news!

Recouping the cost of CAM treatments not covered by regular insurance

See ANH-USA's [newsletter article and Action Alert](#) about the new Retirement Health Investment Act of 2011 . This new legislation would expand Health Savings Accounts (HSAs) and Flexible Spending Arrangements (FSAs) coverage of all forms of dietary supplements.

Other USA News

The following may also be of interest to US practitioners:

[American Diabetes Association's Guidelines Are Killing Diabetics!](#)

[Genetically Engineered Food Alters Our Digestive Systems!](#)

[Vaccine Mania](#)

[When It Comes to Natural Health for Children, We're Living in a Police State](#)

[Lyme Disease: Misdiagnosed, Underreported—and Epidemic](#)

[Newsweek Publishes Disgraceful Article on Antioxidants \(Action Alert\)](#)

[Survey Results: Supplements, Diet, and Exercise Top the List of "Alternative" Therapies!](#)

AUSTRALASIA

New Zealand: Regulatory Impact Statement for Natural Health Products Bill

In June, the New Zealand Ministry of Health published its [Regulatory Impact Statement](#) relating to the development of a Natural Health Products Bill. The statement has been issued following [public consultation](#).

The statement considers what functions, powers, and funding mechanisms may be required by the regulator for the operation of a cost-effective regulatory scheme that, *“Gives New Zealanders confidence that the natural health products they use are safe, true to claim and true to label”*.

AIMA President Prof Kerryn Phelps appointed to Order of Australia

Professor Kerryn Phelps, President of the [Australasian Integrative Medical Association Inc](#) (AIMA) and, since the year 2000, the first female president of the Australian Medical Association, has been appointed to the [Order of Australia](#) *“In recognition of her service to the medical field and for her exemplary leadership qualities demonstrated in the areas of education and community health as a General Practitioner”*.

Since the 1980s “Dr Kerryn” (as she is known to many) has been a familiar face in the Australian media. She strives to bring the message of integrative medicine, public health and human rights to the public at large. Our congratulations to Professor Phelps.

Japan endurance tested to the limit

On 11 March 2011, a magnitude 9 earthquake struck off Japan's north-east coast, triggering a chain of events that resulted in [mass devastation](#). The resulting tsunami and catastrophic damage to the Fukushima power plant tested the endurance of the Japanese people to the limit. It is likely that Japan will take years to recover.

Our thoughts are with the Japanese people and our collaborating Japanese practitioners who, together with their families, may have been caught up in this terrible tragedy. We extend every sympathy to all our contacts in Japan at this difficult time.

* * *

We thank you for your collaboration, contributions and support as we face the mounting challenges and worldwide threats to natural health. Please forward this newsletter to your members, colleagues and other interested parties.

Should your organisation of practitioners be interested in [collaborating](#) with ANH International on any of these issues, we would very much like to hear from you. Please email Yvonne England, our practitioner liaison specialist, at yvonne@anh-europe.org.

In health, naturally.

A handwritten signature in black ink, reading "Y England". The signature is written in a cursive, flowing style.

Yvonne England
Practitioner Liaison

For further information:

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