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THE FIRST TRULY INDEPENDENT WATCHDOG FOR THOSE WORKING WITH NATURAL AROMATIC MATERIALS

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Traditional Herbal Medicine Under Threat.

The purpose of this Cropwatch emergency mailing is primarily to ask all of you to seriously consider signing the *Save Our Herbs* petition at http://www.gopetition.com/petitions/support-herbal-medicine.html This organisation not only campaigns on behalf of the general public, but also represents a very significant proportion of medical herbalists of both Eastern and Western traditions, practising in the UK.

Time is very short - if you want to support this very worthy campaign ensuring the continued availability of safe Herbal Medicinal Products, the continued free use of a wide range of our safe endemic & imported Herbs by ordinary people according to our traditions, preventing the takeover of small Herbal Medicine Suppliers by pharmaceutical concerns, & opposition to Statutory Regulation of Herbalists, you will need to sign the petition by 31st October 2009.

The *Save Our Herbs* campaign's official website can be found at http://www.saveourherbs.org.uk/index.html and provides a wealth of background information to this potential crisis for Herbal Medicine. Cropwatch strongly recommends you to read through the comprehensive information to be found there.

Cropwatch's Own View.

There are a number of inevitable consequences for Traditional Herbal Medicine as a result of the implementation of the EU Commission's *Traditional Herbal Medicinal Products Directive 2004/24/EC*, which came into force on 30th April 2004.

§1. Traditional Herbal Medicinal Products (THMP's). All THMP's placed on the market post the implementation date of the new EU

legislation, must have a national authorisation to be marketed, and whilst several EU member countries have had national schemes in place, the UK has previously enjoyed a virtually unregulated market. In the UK, for products already on the market prior to the introduction of this legislation, marketing concerns have until 30th April 2011 to obtain authorisation (from the Medicines and Healthcare products Regulatory Agency - MHRA) and to work to GMP. The MHRA's Traditional Herbal Registration Scheme, and its relative lack of uptake – undoubtedly due to the excessive costs involved (as shown by the low cumulative total of THR registrations) can be viewed at http://www.mhra.gov.uk/Howweregulate/Medicines/Herbalmedicines/PlacingaherbalmedicineontheUKmarket/TraditionalHerbalMedicinesRegistrationScheme/index.htm As we have witnessed in other seen-to-fail & discriminatory areas of EU legislation (that pertaining to Biocides regulation for example), unnecessary, over-intrusive and crippling financial burdens are placed on the SME's which market natural products, a situation which plays straight into the hands of the pharmaceutical / chemical companies. It should also be remembered that the MHRA themselves have been severely criticised as being too close to the pharmaceutical industry (e.g. in *House of Commons Health Committee Report* (2005) entitled 'The Influence of the Pharmaceutical Industry':

"A House of Commons Health Committee Report from 2005, entitled 'The Influence of the Pharmaceutical Industry' is highly critical of the MHRA and its close relationship with the pharmaceutical industry. It states, '(t)here are regular interchanges of staff, common policy objectives, agreed processes, shared perspectives and routine contact and consultation. Many of the senior staff of the MHRA have previously worked with the industry …'[1] It is therefore doubtful whether the MHRA can be trusted to serve the best interests of herbal medicines, herbalists and their patients".

For a breakdown of expected MHRA fees for THMP's, please refer to a document drawn up by Dave Blackwell of Herbs4Healing Ltd. under Appendix A at the end of this document, and reproduced with his kind permission.

§2. The Possible Illegality of Actions by Regulatory Officials Meddling with the Free Availability of Natural Remedies in the UK.

The UK differs from other European Member States, since there has long been a legal recognition of Herbal Practitioners, dating back to

Henry VIII's Charter, which defines a Herbalist and the right to practice & minister:

Common Law set down by Henry VIII defines a herbalist '…*henceforth it shall be lawful to every Person being the King's subject. having Knowledge and Experience of the Nature of Herbs, Roots, and Waters, or of the Operation of the same, by Speculation or Practice, within any part of the Realm of England, or within any other the King's Dominions, to practice, use, and minister in…'*

(see Watt 2009: http://www.aromamedical.com/articles/traditional-herbalists.htm, reproduced by kind permission). Cropwatch understands this Charter has never been repealed.

It should also be remembered that there is a clause in the Treaty of Rome of 25th March 1957 which can be interpreted as preventing interference with the availability of natural remedies: "2. The Union shall respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law." Watt (2001) discusses the validity of the above argument and further protections of natural remedies afforded by other clauses in the Treaty of Rome at http://www.aromamedical.com/articles/mlx249.html (scroll down to "Controls on Natural Remedies."

The interference with free availability of natural herbs and medicines also impacts on religious freedom & worship and use of herbs in both the Islamic and Judaeo-Christian traditions. Cropwatch understands that representations to Ministers / MP's by a delegation representing views of individual members of the Islamic and Christian faiths respectively, are in progress, in order to avert any possibility of the prospect of religious or cultural discrimination by the regulatory authorities.

§3. Statutory Regulation of (the Title & Function of) Herbalists.

A Consultation Document was published by the Department of Health (DH) of the UK Government on 3rd August 2009: *A joint consultation on the Report to Ministers from the DH Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional*

Medicine Systems Practised in the UK. The consultation period ends on 3rd Nov 2009. The *Save Our Herbs* campaign has produced a draft response to the consultation at http://www.saveourherbs.org.uk/files/Download/Response%20To%20Consultation%20Document.pdf which Cropwatch strongly recommends you read.

We are told by the Department of Health (DH) that the purpose of Statutory Regulation (SR) is / was to safeguard public safety but many herbal practitioners would maintain that this is a nonsense, since existing self-regulation is already proven adequate. *The Pitillo Report* (see below) further states: "Statutory regulation can more effectively assure the standards of those regulated, protecting the public from poor or bad practice, because legal sanctions exist to remove individuals from a register. Statutory regulatory bodies determine standards of practice and competence." But as Cropwatch pointed out in 2008, CAM is not the issue. The UK-based inquiry started in 2000, decided that the medical practitioner Dr Harold Shipman allegedly killed up to 250 of his patients, some 218 of whom have been subsequently identified. Similarly the confidence & assurance in health officials supposedly assured by regulation did not help the victims of Nurse Beverly Allit, knicknamed the 'Angel of Death' by the popular press. Health care authorities had to subsequently carry out heavy modifications to medical practice, belatedly increasing patient protection. Conversely, we are not aware that any practicing Herbalist has killed or injured anybody in the UK (an MHPRA document (July 2008) "Public Health Risks with Herbal Medicine: An Overview" only identified (only) a single major incident, in a Belgian slimming clinic, where an irresponsibly prescribed herb of the *Aristolochia* spp. resulted in 100 women developing kidney failure many of whom allegedly went on to develop cancer). Further, in spite of 22 million annual visits to herbalists in the UK (Thomas *et al*. 2001 thro' *The Pitillo Report*) and with one in three US citizens taking herbal medicines on a regular basis, no safety assessment of herbal medicine has ever taken place, either in the UK or at an international level. Attempts to demonize widely used herbal medicines such as St. Johns Wort *Hypericum perforatum* by the pharmaceutical industry, pale into insignificance when it is realised that the herbal drug has been found to be as effective as major conventional synthetic anti-depressants, and to have fewer side-effects (Linde *et al* (2008)

Cochrane Database Syst Rev **8** (4)). In conclusion, under the government's own protocol, before Statutory Regulation can be established, a risk assessment tool for herbal medicine would have to be established, and no such assessment tool exists. There is also a requirement for an established knowledgebase to be in place, and this is also not established.

On the other hand, with regard to conventional medicine, for some curious reason we hear relatively little in the media about the statistics surrounding the failure of MD's working in the National Health Service (NHS) to correctly diagnose & prescribe the appropriate treatment for a given patient's ills (a major concern). The British Medical Journal (BMJ) Evidence Centre at http://clinicalevidence.bmj.com/ceweb/about/knowledge.jsp reveals that of around 2500 [commonly used NHS] treatments covered, 13% are rated as beneficial, 23% likely to be beneficial, 8% as trade off between benefits and harms, 6% unlikely to be beneficial, 4% likely to be ineffective or harmful, and 46%, the largest proportion, as unknown effectiveness.

Further, tens of thousands of patients die or suffer serious side-effects from certain prescribed (and by now, notorious) pharmaceuticals. It has been admitted that in the decade up to the year 2007, 80,000 patients had died from iatrogenic disease and that a further £46 million had been spent by the NHS on treating the survivors. Since that time reports have been issued that this state of affairs has further deteriorated, in part blaming the increasingly complex MHRA approved drug regimes employed. By comparison, those therapies now being attacked with the threat of regulation are becoming ever increasingly safer! (Information provided by Robert Scott).

Finally, let us turn to the darkly hilarious but thorough reporting of an extensive study by the *Union of Concerned Scientists* to the effect that embarking on a course of conventional drug treatment appears to statistically increase the chances of shortening your life. This is quite aside from the serious chances of dying or losing limbs from hospital acquired infections, or recent media reports of lack of care & attention and even cruelty shown towards elderly NHS patients. Yes, the conventional medical profession / NHS is in serious need of effective statutory regulation, whereas any need for increased

regulation of CAM is, by comparison, not only completely disproportionate to the degree of health risk posed, but, is essentially, nothing but a sideshow, and a waste of taxpayers money.

4. The Government Reconsiders the Need for Statutory Regulation.

There are some strong signs that the Government is re-examining any need for the imposition of Statutory Regulation (SR) of Herbalists whatsoever (in spite of a House of Lords Select Committee recommendation and the recommendation of three DH working groups in favour of SR). At the same time they are apparently reconsidering any need and the practicality of changes to the 1968 Medicines Act Section 12.1 (bear with us: this is an exemption from various medicines licensing requirements in the Medicines Act which allows herbal practitioners to prepare or obtain from a third party, unlicensed herbal medicines to meet individual patient needs identified in a consultation). Instead some reports indicate that they are considering a less severe licensing system, perhaps based more around self-regulation or self-licensing. This follows the publication of the *Report to Ministers from The Department of Health Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK* May 2008 ('*The Pitillo Report*') which can be accessed by following links from (www.dh.gov.uk/en/consultations/liveconsultations/DH_103567).
However, one of the recommendations of the above report is that Herbal Medicine, Acupuncture and Traditional Chinese Medicine (TCM) should come under statutory regulation by the Health Professionals Council (HPC), a body totally unsuited to the task.

It was pointed out by Robert Scott in a letter to the Health Authorities (seen by Cropwatch), that the proposal to regulate Herbal Medicine by Mr. Marc Seale, registrar of the HPC, was made after aggressive lobbying by the chairman (a certain Mr. Michael McIntyre) of the European Herbal Traditional Practitioners Association (EHTPA) who sat as one of three stakeholders on the committee chaired by Professor Pittilo mentioned above. The recommendation to 'strategy regulate' was originally sent by Marc Seale to Alan Johnson in his role as the previous Secretary of State, although we believe the matter was handled by Ben Bradshaw a junior Minister of State at the Department of Health. It appears that both these gentlemen have

now been transferred to different departments. But to quote from the letter mentioned above:

“The chairman of the EHTPA, by his own admission, had a major influence on the Pittilo report. As he is also closely associated with the National Institute of Medical Herbalists (NIMH), this establishes a somewhat troublesome incestuous link between these organisations, which jeopardises the integrity of the final report.

Although the EHTPA likes to put forward that its stance in favour of statutory regulation is supported by the majority of practising herbalists, this claim is not supported by their voting record. The largest body within the EHTPA certainly is NIMH, but only a ridiculously small amount of its membership actually voted in support of this move. The vast majority either abstained or voted against. The membership of the Unified Register of Herbal Practitioners, another organisation that is a member of the EHTPA, was threatened with expulsion from their professional register if they voted against this proposition.

The lack of support for statutory regulation from the membership of URHP had even been acknowledged in writing by the chairman of the EHTPA.”

These extracts seen by Cropwatch only touch the tip of the iceberg regarding the political manoeuvring and ‘behind the scenes’ power games invisible to the hapless regulatory officials who are only served up selected titbits by those players who would seek to control the direction of the regulation of Herbal Medicine. If Cropwatch can find the time, we may open this can of worms further and dissect the odious contents a little later on.

As you can gather then, the basis of the HPC’s support for Statutory Regulation based on the recommendations of the above report is therefore totally undermined – not only has it failed to take into consideration the unique character of Traditional Herbal Medicine but it is also in danger of acting contrary to the principles of the Islamic & Judaeo-Christian religions (see §2 above).

Thanks to Martin Watt & Robert Scott for kind permission to include their material.

Appendix A – by kind permission of David Blackwell.

CRITIQUE OF THMPD AND ITS IMPLEMENTATION IN THE UK

The latest information and detailed explanation on costs are attached.

Dried Herbs and simple Tinctures (Reduced categories I and II)
Many herbal suppliers currently offer a wide range of dried herbs or tinctures for direct sale to the public (e.g. Baldwins and many internet shops). The fee per item (£577 - £864 every 3 years) plus other costs such as inspection and preparation of dossiers will mean that many raw herbs and simple tinctures will cease to be available to the public. The costs are considerably higher where a herb has not previously been included in a product which has been granted a MA or THR, which the vast majority in the western herbal pharmacopoeia have not. In this case the fees rise to an eye-watering £5,185 per herb/tincture. Each different preparation requires a THR. This means that if you supply a single herb as a dried herb (tea), powder, capsules, tinctures of different strengths, alcohol-free extracts, fluid extracts, infused oils and essential oils, plus the organic versions if marketed separately, each would require a separate application. For example Baldwins currently offer in the region of 550 products of which between 10-15% will be considered for the Reduced categories, while the rest will be Complex i.e new registrations. This adds up to an estimated £2,600,000 initially then £360,000 every 3 years thereafter.

This is a very unfair system, since the first to apply for a previously unregistered product will have to pay the full cost (Complex), while subsequent applications will fall into the Reduced category.

Herbal Remedies (Reduced categories I and II) - *usually referred to as Complexes, but this term is avoided to avoid confusion with the THR category*
In theory this applies in a similar manner as for simples (above), but in most cases will be subject to higher fees if there are more than 3 ingredients, ranging from £864 for teas to £1,297 for other preparations and £7,779[1] for previously unregistered ingredients. However Herbs Hands Healing have been told that it will not be possible to register very complex products and to consider issuing them as kits containing all the ingredients separately. The MHRA Public Assessment Reports reveal that where a product includes 2 or more active ingredients genotoxicity data will need to be provided, at least by the time the registration has to be renewed. EC genotoxicity testing involves expensive in vitro and in vivo (live animal) procedures. The assumption here is that combinations of herbs pose a significantly elevated risk and ignores the long history of herb combining and the lack of evidence to suggest that a potential problem exists. If we compare hospitalizations and deaths through food

[1] Applies to combinations of 2 or more ingredients

consumption (e.g. allergic reactions and food poisoning together with the health risks of long term poor food choices) with that arising from the use of herbs, it is clear that food is far more dangerous. Yet it is ludicrous to imagine a time when a simple aubergine bake in tomato sauce with oregano, black pepper, salt and topped with cheese could be subjected to similar concerns and regulations, but here it is happening with herbal medicines. Also we are well aware of the limitations of such testing when it comes to protecting the public from unforeseen adverse effects, as has happened with many pharmaceuticals.

It is anticipated that most specialist herbal suppliers, which can be classed as small to medium businesses, will be unable to finance the registration of their existing range of products and those consulted have come to the conclusion that they will have to wind up their businesses.

Oriental and other World Herbs

Many products will fall foul of the 15 year rule. This includes complex products and herbs from traditions such as Ayurveda and Unani-Tibb, which have no long-established OTC history in the EC. TCM products are more widely available in the UK and tend towards traditional i.e. fixed formulations, however it may still be difficult to establish 15 years use in many instances. Furthermore the "applicant and registration holder *must* be established in the Community", meaning that the onus falls upon importers to arrange THRs. This means that ethnic communities and those who show a preference for oriental medicines are likely to be more disadvantaged by the new rules.

Potential Outcomes

The regulations will undoubtedly change the face of herbal medicine within the UK. It is anticipated that there will be an upsurge in the marketing of a small range of commercially viable herbal products; those that have entered the wider public consciousness and which have gained a reputation as being cures for certain conditions. Examples would be Black Cohosh for the menopause, Feverfew for migraines, Valerian for stress, Echinacea for colds etc. Other herbal ingredients and remedies are likely to disappear from the nation's shelves or be drastically reduced in range. There will be a shift in public perception of herbal medicine towards a more pharmaceutical model where herbs are treated as drugs for specific conditions rather than to treat individual symptom patterns. THMPD will also enable mass marketing of products and will usher in a transition towards supermarkets and chemists as the primary outlets.

Many existing businesses will be severely impacted by the new regulations (wholesalers, manufacturers and retailers) and it is envisaged that many will close as a result, either as April 2011 arrives in the following 3-5 years. The impact of this restructuring of the herbal industry will be felt by herbal practitioners in 2 ways. Firstly the increased demand for certain 'popular' herbs

and the buying power of larger corporations will lead to an inevitable price rise and possible supply problems for these. Secondly, the contraction in demand for other less popular herbs due to the closure of businesses may see a reduction in the range stocked by wholesalers. It is impossible to foresee the full consequences of this, just as no one predicted the sharp rise in world food prices and shortages caused by biofuel production.

The effects could be devastating. Without wishing to be alarmist, the vast majority of small to medium UK herbal businesses could rapidly disappear, leaving many unemployed. Pharmaceutical companies, Chemists and Supermarkets will gain from increased freedom to market products and will no doubt increase their market share and profits. It's somewhat akin to selling mineral and timber extraction rights in the Amazon; the big conglomerates move in and extract everything of value, leaving behind cultural and environmental devastation.

The system is unwieldy, expensive, overly bureaucratic and unnecessary. If anyone truly believes this will protect the public, they are sadly mistaken. There is simply no evidence that there is any significant health risk to be protected from, plus it will be impossible to prevent internet purchases from abroad, thereby creating an uncontrolled marketplace where before there were responsible UK companies who were subject to regulation.

MHRA Charges for THMPD Registration, not including site inspections, stability testing, genotoxicity testing or other miscellaneous costs

CATEGORY	**£ FEE**
Standard All products unless Reduced or Complex	
3 or fewer existing herbal active ingredients	2,593
More than 3 existing herbal active ingredients	3,890
Reduced	
Category I *Herbal teas, excluding ingredients not previously registered**	
3 or fewer existing herbal active ingredients	577
More than 3 existing herbal active ingredients	864
Category II *Tinctures, Essential Oils, Oils, or Capsules, excluding ingredients not previously registered**	
3 or fewer existing herbal active ingredients	864
More than 3 existing herbal active ingredients	1,297
Complex* *Applies where an active ingredient has not previously been included in a*	

medicinal product which has been granted a MA or THR	
Single new herbal active ingredient	5,185
2 or more new herbal active ingredients	7,779

The definitions for fees categories are as follows:

"**Reduced registration application category I**" means an application other than a complex registration application for a traditional herbal registration relating to a medicinal product which is presented in the form of a herbal tea;
"**Reduced registration application category II**" means an application, other than a complex registration application, or a traditional herbal registration where the application falls within one of the descriptions specified in sub-paragraphs (a) to (d) as follows -
(a) the application relates to a medicinal product which is presented in the form of a herbal tincture;
(b) the application relates to a medicinal product which is presented in the form of an essential oil;
(c) the application relates to a medicinal product which is presented in the form of a fatty oil; or
(d) the application relates to a medicinal product which contains only herbal substances in a capsule;
"**Standard registration application**" means any application for the grant of a traditional herbal registration which is not a complex registration application, a reduced application category I, a reduced registration application category II or a change of ownership application;
"**Complex registration application**" means an application for a traditional herbal registration relating to a medicinal product containing an active ingredient that has not previously been included as an active ingredient in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted