



The European Herbal and Traditional Medicine Practitioners Association (EHTPA)

What is it?

The EHTPA is an umbrella body which represents professional associations of herbal/traditional medicine practitioners offering variously western herbal medicine, Chinese herbal medicine, Ayurveda and traditional Tibetan medicine. The EHTPA is dedicated to the development of herbal/traditional medicine, preserving and enhancing the legal basis of practice across EU Member States and promoting best practice throughout the traditions. In particular it is working for legal recognition for herbal medicine practice in the UK (and its devolved Parliament and Assemblies) and the EU.

EHTPA administration

- The EHTPA is a company limited by guarantee.
- The EHTPA holds an annual general meeting and quarterly Council meetings.
- EHTPA Officers are: Chair; Administrator; Chairs of Finance and General Purposes Committee, Education Committee and Accreditation Board; Company Secretary and Finance Officer
- Each professional association (PA) that comprises the EHTPA is represented by two members on the EHTPA Council and these representatives are directors of the EHTPA.
- Each professional association is represented on the EHTPA Education Committee
- Membership of the EHTPA Accreditation Board includes practitioners from professional associations.
- Professional association representatives on Council receive monthly Profit & Loss and Balance Sheet reports. Annual Accounts are received at the EHTPA AGM and are filed at Companies House.
- The Finance Officer and committee Chairs are present at Council meetings to answer any questions relating to their areas of responsibility.

Why was the EHTPA founded?

- The EHTPA was founded in 1993 when it became clear that with the development of medicines and other legislation through the European Union (EU), the legislative framework under which herbal medicine was practised in the UK and Europe was likely to undergo radical change. In 1994 the MHRA (then the MCA) announced that in signing up to the main pharmaceutical directive (then called 65/65/EEC), the government had effectively annulled section 12(1) and (2) of the 1968 Medicines Act. There followed a full-scale political campaign to reverse this ruling in which a nascent EHTPA together with the BHMA and NIMH campaigned to change the

government's ruling which led to a government announcement that, as herbal medicines were traditionally produced, they were not subject to Directive 65/65/EEC and so did not require a market authorisation.

- However following this, the MCA advised the EHTPA that this ruling was unlikely to be legally sustainable in the long term and another solution must be found.

Statutory self regulation

- As far as OTC products were concerned, the proposed solution was the Traditional Herbal Medicinal Products Directive (THMPD) that passed into law in 2004. For practitioners the Department of Health (DH) proposed to work with the profession towards statutory self regulation (SSR) which had been granted to the osteopaths in 1993. **The DH advised that for SSR to be granted, herbalists of all traditions should work together towards this end.**
- Since that time the chief aim of the EHTPA- mandated by all of its constituent professional associations - has been to achieve statutory regulation. Statutory self regulation was developed into statutory regulation (SR) after the Shipman disaster when professions were seen to need independent public scrutiny rather than be subject to regulation by a purely professional body. Such regulation for herbal medicine practice was backed by the House of Lords' Science and Technology Report (2000) and two DH working groups in 1993 and 2008. Two formal DH public consultations also demonstrated overwhelming public support for statutory regulation of practitioners of herbal medicine.

Benefits of EHTPA membership

Professional Unity

- The Department of Health (DH) and Medicines and Healthcare products Regulatory Agency (MHRA) have made it clear that a prerequisite of statutory regulation (see accompanying document on the need for statutory regulation), requires that there is unity amongst the majority of practitioners practising herbal medicine. The CEO of the Health and Care Professions Council (HCPC), the body designated as the statutory regulator if statutory regulation goes ahead, has recently reiterated at the DH/MHRA Working Group that professional unity is essential for statutory regulation to go ahead. The EHTPA is the one body that can achieve this synergy.

Working together to promote unity –

The EHTPA is...

- a member of the UK Herbal Forum which is an association of herbal practitioners, manufacturers and suppliers that regularly meets with the MHRA to discuss herbal regulation, quality assurance and supply matters.
- currently discussing with the profession and herb suppliers how best to assure the quality control of herbal supply to practitioners. For example, it held a one day conference at Kew on supply matters in March 2014 (see below).
- brokering agreements across the professions on issues pertinent to the achievement of SR: eg professional association membership criteria and factors influencing fitness to practise such as CPD programmes.
- working with member professional associations to bring the standards of proficiency procedures as well as dispensing standards to a common standard that will be capable

of transfer to the HCPC (the proposed statutory regulator) when statutory regulation occurs.

- working with professional associations to agree common standards of training and education (the common core curriculum). The EHTPA accreditation board was established in 2000 and details of the accreditation process were supported by and included in the 2008 Pittilo Report to Government. EHTPA accredited courses in Chinese and/or Western herbal medicine are offered at Lincoln College/Lincoln University, Middlesex University, the Northern College of Acupuncture, the University of East London and the University of Westminster.

In summary

- Without SR there is likely to be a free for all in which voluntary registers and in-house training programmes of unknown academic level and quality proliferate. The absence of independent external scrutiny in such institutions will make it increasingly difficult to ensure that prospective students make informed choices about the quality of the training offered and the range of proficiencies required to practise safely and effectively (For further information about statutory regulation, please refer to the EHTPA companion document on statutory regulation).

Influencing UK decision makers

The EHTPA...

- has been the lead organisation in negotiating with the DH about herbal statutory regulation. Its Chair gave evidence in person to the House of Lords' Select Committee on Science and Technology in 2000, the report of which called for the statutory regulation of herbal medicine practitioners. Subsequently, the EHTPA played a major role in the two Pittilo reports in 2003 and 2008 respectively as well as participating in the Report of the Working Group on Extending Professional Regulation set up by the UK Government in 2006. The EHTPA is currently represented on the Herbal Working Group under the Chairmanship of Professor David Walker considering herbal practitioner regulation (see below).
- has initiated a research project that saw the publication of 'Scoping the Evidence for the Effectiveness of Herbal Medicines' in January 2014 (see also below). This data is being updated on a regular basis.
- publically represents the herbal professions in their several traditional forms. This involves PR work, writing to Ministers, Civil Servants and political supporters. It has sought legal opinion when necessary in order to negotiate with the government. The EHTPA Chair liaises with the Prince of Wales' office; the support of the Prince of Wales for appropriate regulation of herbal medicine is well known. The EHTPA Chairman regularly presents reports to Council members to update them on these matters.

Influencing Europe

- The EHTPA has worked with associated member professional associations in Ireland, Denmark and Italy to help these organisations negotiate with their Member States to gain and maintain rights for practitioners to practise herbal medicine. Having associate member professional associations, gives the EHTPA a necessary EU profile to enable it to be represented and heard at EU level, within the European Commission, the European Parliament and the European Medicines Agency as well as by WHO.
- As a result of this work and its profile, the EHTPA was designated as one of only 11 organisations from EU Member States to form the CAMbrella advisory board.

CAMBrella was funded by the European Commission to evaluate the patient demands for CAM and its use in Europe, to review the legal status of CAM in Europe, to explore the needs and attitudes of the EU citizens with respect to CAM and to propose an appropriate research strategy to develop understanding of CAM use and its effectiveness within the EU. The influential CAMbrella report was published in December 2012 see http://cordis.europa.eu/result/rcn/57185_en.html.

- Such EU involvement is an important function of EHTPA work which has seen it negotiate with the Commission and European Medicines Agency over the introduction of the Traditional Herbal Medicinal Products Directive (THMPD) and lobby the European Parliament from the time of the European Parliament Resolution on the Status of Non-Conventional Medicine (the Collins Report) in 1997.
- The EHTPA is now working with EUROCAM at EU level. The Chair of the EHTPA attends regular meetings of this organisation in Brussels. This is an association of European Complementary and Alternative Medicine (CAM) organisations including patients, doctors and practitioners, providing information about CAM modalities including herbal medicine scoping its current practice and availability as well as its potential future role across the EU. In addition, EUROCAM highlights a number of priority policy action areas to enable CAM therapies to fulfil their significant potential to contribute to the healthcare of citizens throughout the EU. A list of what has been achieved so far by EUROCAM is summarised in the second half of this paper. The EHTPA Chairman regularly presents reports to Council members on such activities.

2014 and beyond

- The EHTPA operates in a turbulent political environment in which it responds to the constantly shifting sands of government policy. Budget values for 2014 necessarily are based on the actual values for 2013 since these are the only realistic figures known at the beginning of the accounting year on which to estimate the cost of the coming year's work
- Future plans of the EHTPA are obviously dependent on what happens with the current review undertaken by the Dept. Chief Medical Officer of Health and on the wishes of EHTPA constituent professional associations. When post regulation plans have been discussed in the EHTPA Council there has been general agreement that there will be a need for one strong voice representing the profession if it is to be heard by the new regulator and by politicians and civil servants as well as by opinion formers in the UK and in Europe. The EHTPA's contribution to date is impressive; it has unique experience to offer and is well placed to fulfil this role.

Details of the main work and achievements of the EHTPA during 2013 and 2014

2013

Throughout 2013 the EHTPA made every effort to work with the Department of Health (DH) and the Medicines and Healthcare products Regulatory Agency (MHRA) to enable herbal/traditional medicine practitioners to become statutorily regulated. During 2013, it became apparent that the DH and the Minister responsible for herbal regulation, Dan Poulter, were no longer committed to the timetable for statutory regulation of our sector as outlined in the public announcement by the then Secretary of State for Health, Andrew Lansley, in

February 2011. The reasons for this were not explained despite many efforts to elicit an answer about this from the Minister.

However, progress on this front was made by a renewed vigorous letter campaign organised by the EHTPA to MPs and the DH by our supporters and an online petition calling on the Secretary of State for Health to undertake herbal statutory regulation that eventually achieved over 8000 signatures in support of herbal statutory regulation.

On April 24th 2012 the EHTPA organised a mass lobby of Parliament and this was followed by a short debate on herbal regulation at the House of Lords in which the government was represented by the Baroness Northover.¹ Following the debate, the Baroness Northover wrote to Lord Pearson (who had called the debate on the EHTPA's behalf) mentioning that there were concerns following an European Court of Justice report regarding the use of unlicensed medicines by Poland as to how this might impact on the use of unlicensed medicines supplied from third parties for UK herbalists following statutory regulation. In her letter, the Baroness acknowledged that the EHTPA had obtained legal opinion about this from an expert lawyer, Mr David Reissner. This independent counsel sought by the EHTPA advised that ECJ judgement re the Polish matter was no bar to the use of third party supply of medicines under the specials arrangement (Article 5.1 of Directive 2001/83/EC).

On 9th July 2013, as a result of further lobbying by the EHTPA, a further debate on this subject took place in the House of Commons at which Dan Poulter, the Minister responsible for regulation, announced his intention to set up another working group to look again at the best way to create a legal framework for the ongoing practice of herbal medicine in the UK. Dr. Poulter said; "To ensure that we take forward the matter effectively, we want to bring together experts and interested parties from all sides of the debate to form a working group that will gather evidence and consider all the viable options in more detail... to ensure that the legislation is fit for purpose."

In October 2013, the Chair of the EHTPA together with Dr Michael Dixon, Chair of the NHS Alliance and the College of Medicine, met with a senior civil servant at the DH who assured the Chair that statutory regulation was still on the agenda and that the new working group would meet before Christmas. In the event, the first meeting of the herbal working took place in late January 2014.

In Europe, the EHTPA continued working with EUROCAM, a group of likeminded complementary practitioner organisations working at an EU level dedicated to building on the work of CAMbrella – a two year fact finding project funded by the European Commission to review the demand and delivery of CAM therapies across the European Union. The EHTPA was an advisory group to CAMbrella which published its report in 2012. In 2013 EUROCAM (in which the EHTPA participated) determined to:

1. Build on the CAMbrella proposals and present a professional platform representing CAM therapies at EU level.
2. Promulgate research into CAM seeking to explore effectiveness rather than simply employ double blind CC trials.
3. Offer a presence in Brussels to lobby for CAM. This can be furthered by the use of the IVAA office where this meeting was held. This can offer a meeting place and

¹ <http://www.publications.parliament.uk/pa/ld201213/ldhansrd/text/130424-gc0001.htm#13042481000224>

secretariat to run meetings of EUROCAM. Teleconferences help to keep costs of running this group down.

4. Work together on an ad hoc – project lead basis with each project separately scoped and costed.
5. Seek to offer a point of information on CAM
6. Lobby MEPs and the EU Commission to alter medicines law to enable practitioners and patients to access medicines used in CAM practice e.g. herbals.
7. Work to assure the availability of such medicines having relations with the EMA and the HMPC
8. Seek to establish training standards for each modality
9. Gain funding for this work where possible.

EUROCAM's work also extended to running conferences to brief the Commission and MEPs. In June 2013, the Chair of the EHTPA participated in a presentation to Commissioner Tonio Borg responsible for Health and Consumer Policy on the scope of CAM in the EU (the EHTPA Chair presented on herbal medicine). See also below for further EUROCAM work in 2014.

Across Europe, the EHTPA has continued to keep its associate member organisations in Ireland, Denmark and Italy abreast of European developments.

During 2013 the EHTPA undertook a scoping study to review research into herbal medicine. After consulting a group of selected experts in a meeting arranged by the EHTPA, a plan was formulated to take this forward, interviews were conducted and a researcher was appointed to lead the project. See below for detail of resulting publication in January 2014.

The Science and Technology Committee of the House of Commons announced that it was to hold an inquiry into antimicrobial resistance and in November 2013, the Chair submitted a paper to the inquiry based on the research work carried out in the Scoping Study. This was published on the House of Commons Select Committee website and the EHTPA Chair was invited to give oral evidence to the House of Commons's Select Committee on Science & Technology.

On November 9th, 2013 a conference arranged by 'The Save Herbal Medicine Group' was held at Wolfson College Oxford chaired by the Chair of the EHTPA. EHTPA director, Chris Etheridge also spoke at the conference, which elicited support for the promised herbal regulation.

The EHTPA Chair also had a substantial article published in the winter edition of the journal *Primary Care Today* pressing the case for statutory regulation of herbalists.

In November the Chair was asked to open the new herbal clinic at Middlesex University to serve the Enfield campus.

In December 2013, as previously mentioned, the Chair of the EHTPA met with a senior official from the Department of Health and Dr Michael Dixon to discuss the launch of a new Herbal Working Group by the Minister, Dr Dan Poulter.

2014

In the first week of the New Year, the EHTPA published electronic and hard copy versions of ‘*Scoping the Evidence for the Effectiveness of Herbal Medicines*’ – a study to review research into herbal medicine – the result of a year’s work.

On January 19th an article on statutory regulation of herbal medicine ‘Prince pushes vision for a different NHS’ was published in the *Sunday Telegraph* which was based partly on the article by the Chair of the EHTPA in the journal *Primary Health Care* and reiterated the case for statutory regulation. The Chair of the EHTPA was quoted by the newspaper – see... <http://www.telegraph.co.uk/journalists/laura-donnelly/10576548/Prince-Charles-makes-plea-on-alternative-medicine.html>

On January 13th the EHTPA arranged a meeting of practitioners nominated to the new working group as well as the Chair of the BHMA and that of Herbal Forum in advance of the Working Group’s first meeting at the end of January to discuss the way forward on statutory regulation.

On 23rd January the Chair of the EHTPA attended a Council meeting of the College of Medicine where he gave an update on herbal regulation.

In January the Chair of the EHTPA delivered a report to EHTPA Associate Members as well as Council that included a report on CAM and Horizon 2020 re research funding as well as a updated policy briefing from CAMbrella.

Early in February the Chair of the EHTPA sponsored a letter to the Chair of the Working Group signed by 14 of its members asking for clarification about the legal position regarding herbal medicines supplied to practitioners by independent suppliers and manufacturers.

In February the Chair of the EHTPA wrote an article for the magazine *Caduceus* on the statutory regulation of herbalists.

On 26th February 2014, the EHTPA Chair gave oral evidence to the House of Common’s Select Committee on Science & Technology.

March 7th EHTPA Chair and Administrator attended a meeting at the Herbal Forum to meet with representatives of the MHRA.

March 10th EHTPA Council meeting where the Chair made a full report on work of the Working Group.

March 12th EHTPA Chair attended EUROCAM meeting Brussels

March 19th the EHTPA presented a paper agreed by the EHTPA Council on the Case for Statutory Regulation to Professor David Walker and the members of the working Group.

March 24th EHTPA sponsored a herbal suppliers meeting day at Kew to discuss quality assurance issues. Several presentations on this subject as well as on CITES and plant nomenclature were presented.

On April 1st, the Chair of the EHTPA presented at a EUROCAM one day conference in the European Parliament on herbal medicine and antimicrobial resistance.

17th April Chair of EHTPA, Alison Denham (HMAC), the President of NIMH and others were invited to meet with Professor David Walker to discuss practitioner regulation.

The same day the Chair of the EHTPA together with EHTPA director Emma Farrant met with the MHRA lawyer to discuss the legal issues around herbalists using Article 5.1 of Directive 2001/83/EC if statutorily regulated. The Chair of the EHTPA wrote a report about this important meeting circulated to the Chair of the Working Group, Professor David Walker as well as to all Council members of the EHTPA.

28 April the EHTPA arranged a Conference Call (no 1) with suppliers re herbal supplies and quality assurance (QA) issues.

28th April EHTPA chair wrote a letter to Professor David Walker, Chair of the Working Group entitled ‘The practice of herbal medicine in the UK – a way ahead?’ suggesting some positive ways that herbal regulation can be brought in based on statutory regulation. This letter signed by the Chair of the EHTPA and other members of the WG.

May 1st Working Group 2nd meeting at the MHRA, London

May 12th EHTPA arranged Conference Call (no 2) with suppliers re herbal supplies and QA
May 14th Response to questions from NIMH Council... a paper from the Chair of the EHTPA.

May 18th EHTPA Chair met with the NIMH Council in Exeter

June 22 EHTPA Chair spoke on regulation at Ayurvedic conference, London

July 10 3rd Working Group meeting followed by meeting (EHTPA Chair, Chair of Education committee and Administrator) with principals of New Zealand Wellpark College

June 17th Robust response to article hostile to herbal medicine in the BMJ from the Chair of the EHTPA , Professor Lewith, Andrew Flower and Sarah Price published by the BMJ.

July 14th Meeting at the Department of Health with Chair of the Working Group, Professor Walker together with Emma Farrant

July 16th written report to EHTPA Council regarding the Working Group meeting on July 10th.

July 25th Follow-up letter to Professor David Walker after the meeting with him on 14th July re herbal practitioner regulation providing further suggestions regarding the way forward

On September 12th the EHTPA Chair attended a EUROCAM meeting in Brussels. Over the past 9 months, the EHTPA Chair edited a booklet ‘CAM 2020’. This is now published by EUROCAM, a copy of which has now been sent to every MEP in the European Parliament. A copy of this booklet can be found on the EHTPA website <http://ehtpa.eu/>. EUROCAM has launched a website available at www.cam-europe.eu .