Response to the Recommendations of the Report on the Regulation of Herbal Medicines and Herbal Practitioners 27 March 2015

From the Chair European Herbal Practitioners Association (EHTPA)

A report from the Deputy Chief Medical Officer of Health about the future regulation of herbalists has just been published. Here is our response:

- In 2014 the government convened yet another Working Group to consider the statutory regulation of herbalists (SR)
- There have already been three previous committees that have recommended SR for herbalists
- There have also been two UK wide public consultations about this both of which recorded overwhelming public support for herbal SR.
- In 2011 the Secretary of State for Health announced that SR for herbalists would go ahead.
- Now the government has done a complete U-turn and despite the promise that the Expert Group convened to discuss next steps would be fully consulted has published a new report on herbal regulation written by the Deputy Chief Medical Officer of Health that has decided that SR will not now go ahead.
- The majority of the Expert Group has written to the Health Minister to say they do not agree with this U-turn but their views are being ignored. The Expert Group was not shown a draft of the Report before publication.
- Voluntary regulation is no substitute for SR and cannot assure public choice and public safety.
- The Report suggests that medicinal herbs can be recategorised as foods. If this happens many herbal medicines will no longer be legally available.
- This report fails to recognise robust existing processes and academic standards established by a number of responsible UK herbal voluntary registers.

Response in detail

Foreword

In October 2013, the Chair of EHTPA met with an official from the Department of Health (DH). The meeting was informal but seemingly marked a significant sea change in the attitude of Dan Poulter, the junior health minister appointed to the post in 2012. The official apologised on behalf of the DH to the EHTPA Chair for failure by the DH to communicate with the EHTPA regarding the statutory regulation of herbalists during the preceding year following the previous Secretary of States' public announcement in February 2011 that statutory regulation of herbalists was to go ahead. The official said that a new committee was going to be launched by the DH which would in early 2014 address some technical issues regarding EU law and that statutory regulation of the herbal sector, as promised by the Secretary of State, was still very much on the table. The EHTPA Chair was assured by the official that this new committee (the fourth on this subject since 2000) was not just another delaying tactic by which the minister could kick the subject of herbal statutory regulation even further into the long grass and that, after so much delay, the matter of statutory

regulation would be rapidly resolved. Buoyed up by apologies and promises we committed to the Working Group. This we can now see was a mistake.

The publication of the Report on the Regulation of Herbal Medicines and Herbal Practitioners late on 27 March 2015, on the eve of the dissolution of parliament prior to the general election, proved the undertakings given by the DH worthless. The Terms of Reference of the Committee published by the DH as the Committee met declared *"The group will report with recommendations in 2015 or sooner if it concludes its work before that date."* The Chair of the Working Group, Professor David Walker, told the expert group that he thought the job would be done by Christmas. But political expediency evidently demanded that the Report would be published precisely at a time when its highly controversial findings would be buried under an avalanche of media reportage of the onset of the 2015 general election.

The promise that the Expert Working Group convened by the government would report with recommendations also proved misleading. Although a clear majority of the Working Group favoured statutory regulation, as evidenced by an open letter sent to the Minister signed by more than half the Working Group[1], the DH/MHRA has used the Working Group undemocratically and unilaterally to make recommendations with which the majority of Working Group members fundamentally disagree. The majority views of this Expert Working Group were ignored and, despite assurances to the contrary, a draft of the Report was not shared with the Group before publication. This was contrary to the Terms of Reference of the group and is to be deplored.

The Report from the Deputy Chief Medical Officer of Health for England is described by the DH as "independent" but it is certainly not that. The fact that the Expert Committee were not shown a draft of the Report before it was published clearly demonstrates that this has been a "top down" decision from on high totally ignoring the huge public vote in favour of statutory regulation of herbalists expressed in two UK wide public consultations on this subject run by the DH.

The Nobel prize-winner and economist Milton Friedman famously highlighted the self interest of the medical establishment in limiting entry into medicine[2][3] and here, apparently, is another example. When all is said and done, this report is about who has the right to practise medicine in the UK. Herbalists have fought for their right to do so for centuries and will do so now on behalf of the millions of UK citizens who make regular use of herbal medicine. Herbal medicine is certainly ancient medicine but it has important benefits for citizens of our time. For example, were physicians to use herbs instead of antibiotics for many of the milder infections, we would not now be facing the loss of antibiotic therapy that threatens our very way of life.[4] We herbalists will not give up the fight for statutory regulation of herbal practitioners as the only means of ensuring patient choice and patient safety. Our response to the Report continues to make the case for herbal statutory regulation explaining why so many members of the Expert Group were in favour of this outcome. The Recommendations below are those from the Report; each is followed by our response.

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[1] For this see "Public Statement from dissenting members of the Herbal Practitioner and Medicines Working Group to Department of Health (DH) 28 March 2015" available at http://ehtpa.eu/

[2] Friedman M, Kuznets S. *Income from independent professional practice*. New York: NBER, 1945.

[3] Friedman M. Capitalism and freedom. Chicago: University of Chicago Press, 1962.

[4] http://www.nottingham.ac.uk/news/pressreleases/2015/march/ancientbiotics---a-medieval-remedy-for-modern-day-superbugs.aspx. Accessed 30/03/15.

Recommendation 1
The government should consider the feasibility of a systematic review of herbal ingredients drawing on existing legal frameworks with a view to amending current lists of potent or toxic herbs where sufficient safety concerns are raised. Such a scheme could initially be linked to an accredited voluntary register of practitioners under an umbrella arrangement that could seek accreditation from the Professional Standards Authority for Health and Social Care (PSA) in due course.

Voluntary accreditation under the PSA is no substitute for statutory regulation: Voluntary accreditation of herbal practitioners already exists in the UK via a number of well-run professional associations with decades of experience of delivering training and monitoring fitness to practise of their members. For example, the National Institute of Medical Herbalists has been in existence since 1864, while the Register of Chinese Herbal Medicine was founded in 1985.

However, the essential weakness of voluntary accreditation is that any practitioner disbarred by one of the voluntary registers can leave the register and legally continue to practise outside its jurisdiction. Training institutions that do not wish to submit themselves to independent accreditation can likewise refuse to participate and operate outside the accreditation scheme.

The PSA suffers exactly the same shortcomings that undermine other existing voluntary accreditors since the PSA has no more ability than existing voluntary registers operating in the herbal sector to require herbal practitioners to belong to it or to require that all herbal training institutions adhere to agreed standards of training.

More worryingly, the PSA regulatory option is deceptive, offering the public false security as it appears to have all the powers of a statutory regulating council but in reality in its role as a voluntary accreditor it has none. Because the PSA has another quite separate role to oversee UK statutory regulators of health professionals, the public will undoubtedly confuse its quite separate statutory and voluntary functions and mistakenly perceive that as a voluntary accreditor the PSA can provide the public with effective regulation of herbal practice. In reality this is only possible via statutory regulation.

Weaknesses of voluntary accreditation scheme run by the PSA
Protection of title
- None; any member of the public can call him/herself a herbalist if so he/she so wishes.
- Ex members of the PSA can still use the occupational title.
- For this reason the public will continue to be confused about who is a properly trained and regulated herbalist.

Concerning fitness to practise tribunals run by PSA…
Unlike a statutory regulator, the PSA has no legal power to require that…
- Relevant evidence/information be submitted to its tribunals
- Essential witnesses attend its tribunals.
- Practitioners under investigation attend its tribunals
- Practitioners under investigation do not resign and then continue to practise outside PSA accreditation.

The essential weakness of voluntary accreditation is that any practitioner disbarred by one of the voluntary registers can leave the register and legally continue to practise outside its jurisdiction.

There is no evidence of any harm arising from use by herbalists from these voluntary registers of "current lists of potent or toxic herbs" since their training enables them to use these remedies safely for the benefit of patients. Any review of these herbal medicines should take this into consideration.

Recommendation 2
MHRA, Department of Health and/or other relevant government agencies should review the food lists currently in development and consider whether these could be used to assist the UK's assessment of the status of herbal products.

If appropriate, the feasibility of a UK herbal list, which could assist herbal practitioners' understanding of the regulatory status of herbal ingredients, could be investigated.

Moving forward a mechanism could be established to allow for a regular review.

The notion that herbal medicines can be recategorised as foods is seriously flawed.

Herbal medicines are required by herbal practitioners to treat patients with identifiable diseases. By definition, food supplements are intended to improve health rather than treat disease, i.e. they contribute to the normal functioning of the body. In view of this fundamentally different use of medicines and foods, it is clear that food supplements cannot replace medicines.

While it is true that some Member States have drawn up lists of herbs as foods such as BELFRIT (France, Italy & Belgium) and the STOFFLE list (Germany), these have no legal status in the EU and are not recognised by the European Commission. Many herbal medicines contain chemical constituents (e.g. many alkaloids such as berberine) that are not accepted as having food status in the EU. These herbs cannot simply be recategorised as foods.

Medicines are legally permitted to have risk and benefit whilst no such dispensation is allowed for foods. For this reason, shifting herbal medicines to food status items would severely inhibit herbal practice.

Recommendation 3
The government should consider further the idea or a system that would allow small scale assembly of products off-site on a named patient basis using a 'dispensary type approach.
We agree with Recommendation 3 but this recommendation can best operate when combined with the statutory regulation of herbalists with a built in analysis/assessment of quality and safety in the supply chain of herbs they supply. These considerations can best be achieved by a statutory regulated profession autonomously working closely with the MHRA and The Herbal Medicines Advisory Committee (HMAC).

Recommendation 4

In the longer term the UK government may wish to invite the European Commission to review the operation of the Herbal Directive, as many of the herbal medicinal products used by herbal practitioners in the UK fall outside its scope.

This is a laudable aim, but the European Commission has for several years recognised the shortcoming of the scope of the THMPD and has failed to remedy this deficit. Will anything change?

In its discussion of this recommendation, the Report states *"it is important to recognise that it is now some 10 years since the Directive (i.e. Directive 2004/24/EC – The Traditional Herbal Medicinal Directive - THMPD) giving the sector a long time to adapt to its requirements."* This is misleading as the THMPD was not designed to place herbal medicinal products suitable for professional herbal practitioner use on the market. On the contrary, Directive 2004/24/EC states that traditional herbal medicinal products registered under the THMPD should *"have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment."*

This limitation in the THMPD registration scheme has been openly acknowledged by the European Commission in its report to the Council and the European Parliament in 2008.[5] It noted:
" Medical traditions such as those mentioned above (i.e. traditional Chinese medicine , Ayurveda etc) are based on a holistic approach, and the set of requirements for the simplified registration procedure under Directive 2004/24/EC is not appropriate for a global regulation of such medical practices. The regulation of such traditions would demand a different approach from that introduced by Directive 2004/24/EC. Therefore, the Commission does not envisage extending the scope of the simplified registration procedure to cover traditional medical systems as such. Nevertheless, independently of this report, the suitability of a separate legal framework for products of certain traditions should be assessed."

From 2005 when the DH first published a timetable for the statutory regulation of herbal practitioners until 2013 when the launch of yet another Working Group on this subject was announced, professional herbal practitioners in the UK had been assured by the DH/MHRA that statutory regulation of the sector would go ahead. For example, in 2006 the DH website recorded that *"The Government is committed to the statutory regulation of herbal medicine, acupuncture and traditional Chinese medicine practitioners…. to move gradually towards statutory regulation, probably in 2008/9."*[6] In 2011 the Secretary of State announced that statutory regulation of this sector would proceed immediately and subsequently representatives from the herbal sector met with DH officials to progress this regulatory work.

In December 2006 the MHRA published a discussion paper entitled *"The regulation of unlicensed herbal medicines commissioned by a registered herbalist from a third party to*

[5] COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT concerning the Report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to traditional herbal medicinal products. 2008. (Document on the basis of Article 16i of Directive 2001/83/EC).
[6] file:///C:/Users/Mic/Documents/EHPA/Workforce%20update%20%20The%20Department%20of%20Health%20-%20P&G%20Human%20resources%20and%20training.htm. Accessed 29/03/15.

meet the needs of individual patients: a discussion paper."[7] This paper outlined a proposed route by which UK herbal practitioners could continue to access herbal medicinal products produced off site under Article 5.1 of Directive 2001/83/EC – the main pharmaceutical Directive.
The ongoing failure to provide a legal basis for such off-site facilities to allow the supply herbal products, formerly permitted under Section 12(2) of the Medicines Act of 1968 (recently repealed), is forcing herbal practitioners without dispensary facilities out of business and means that members of the public can no longer access herbal treatment on which they have come to rely.

Recommendation 5
As a first step it would be helpful for the sector organisations to develop an umbrella voluntary register that could support the development of standards and begin to collaborate on the collection of safety data and the establishment of an academic infrastructure to develop training and research. This voluntary register could in due course seek accreditation from the Professional Standards Authority for Health and Social Care (PSA).
and:
Recommendation 6
In order for an evidence based decision to be made about the level of assurance required to ensure public protection, the government should support further research. This should consider evidence that:

- Clarifies the risks to public health associated with herbal medicine practice.
- Assesses how those risks are currently mitigated and whether further intervention is required
- If intervention is required, it must provide an evidence base that informs the rationale for the decision on how risk to public protection will be mitigated
- Looks at the case for assurance of herbal practitioners in the wider context of herbal medicines.

It is a matter of regret that these recommendations (5 & 6) have failed to recognise robust existing processes and academic standards established by a number of responsible UK herbal voluntary registers. The European Herbal Practitioners Association (EHTPA) was launched in 1993 as an umbrella organisation to agree and implement professional, academic and safe standards of practice across the herbal sector to be used as a basis for admission to the voluntary registers of member associations.

EHTPA standards have been used as a basis of accreditation of UK herbal courses to degree standard since 2002/3. For example:

- EHTPA standards of proficiency and practice mirror those adopted by the Health and Care Professions Council, formerly designated as the regulator of herbal practitioners by the DH.
- The EHTPA has developed a Common Core Curriculum operative for more than ten years across the differing herbal traditions. This provides the basis of the work of its highly regarded accreditation board which currently accredits UK university training in herbal medicine.

[7] Paper 6: Reforms of s12(1) of the Medicines Act 1968: the regulation of unlicensed herbal medicines commissioned by a registered practitioner from a third party to meet the needs of individual patients available at http://ehtpa.eu/medicines_legislation/index.html. Accessed 29/03/15.

- Senior practitioners as well as independent board members from higher education are involved at every stage of the accreditation process and decisions independently taken avoiding conflicts of interest.

Voluntary regulatory registers that are members of the EHTPA all subscribe to the adverse event yellow card system operated by the MHRA. The fact that there are relatively few reports of serious adverse events regarding herbal treatment points to the comparative safety of herbal treatment provided by responsible, well trained practitioners.

The weakness of accreditation via the PSA has been highlighted in the response (above) to Recommendation 1. It should be added that PSA standards do not encompass professional or academic accreditation standards and would rely on those provided by the EHTPA and others from the herbal sector. For this reason 'the establishment of an academic infrastructure' would remain in the hands of the herbal profession. There would be no particular additional benefit gained from accreditation by the PSA.

As for research, the Terms of Reference of the Herbal Practitioner and Medicines Working Group to Department of Health (DH) state that *"the group will make recommendations to the government on the way forward"* and that after *"a draft report (had been) completed and shared informally…the group would report with recommendations in 2015 or sooner"*. In the event, the Working Group was never shown any draft of the report before publication. The Report lays emphasis on robust evidence base as a requisite for statutory regulation, yet its terms of reference did not call for this evidence. The section on evidence base (Annex C) contains a list of Cochrane Reviews "selected randomly" which was never shared with the Working Group. Had this occurred, no doubt, the papers on "*Relaxation techniques for pain management in labour*" and "*Non-pharmacological interventions for fatigue in rheumatoid arthritis*" would not have been included while other relevant data, which was not included, would have been provided. Using a random survey of 100 Cochrane Reviews for conventional medicine would probably come to the same conclusion- that the evidence base supporting its practice is weak and further more rigorous research is required. As an example a 2012 review of dental procedures conducted by analysing Cochrane Systematic Reviews (CRS) came to the extraordinary conclusion that *"on the basis of CSRs, the overall quality of evidence can be regarded as low or nonexistent for most of the dental procedures assessed."*[8] Would the author of this Report thus conclude that all dentists should have their statutory regulation annulled? Surely not.

The EHTPA is dedicated to research into the effectiveness of herbal medicine. To this end it has recently published *"Scoping the Evidence for Herbal Medicines"* - a review of existing evidence for herbal treatment of a wide range of common chronic and acute conditions such as cardio-vascular, digestive, O/A, depression, infectious diseases.[9] This document was provided to the Chair of the Working Group but the Report makes no mention of this research work. The EHTPA made a formal submission to the House of Commons Select Committee on Science and Technology in November 2013 and the Chair of the EHTPA gave evidence in person to the Select Committee. The submission based on reliable evidence for the use of herbal medicines to counter antimicrobial resistance can also be accessed on the EHTPA website.[10] Disappointingly, this too received no mention in the Report.

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[8] Faggion CM Jr. Is the evidence supporting dental procedures strong? A survey of Cochrane systematic reviews in oral health. *J Evid Based Dent Pract*. 2012 Sep;12(3):131-134..
[9] Available as a download from http://ehtpa.eu/ Accessed 29/03/15.
[10] IBID

The Pittilo report (2008)[11] emphasised that statutory regulation of the herbal practitioner sector is in the public interest. It said:
"The Steering Group is strongly of the view that the decision to statutorily regulate professions practising herbal medicine and acupuncture is in the public interest. Survey data demonstrates high demand for complementary and alternative medicine. 10.6% of the adult population of England had visited at least one therapist providing any one of the six more established therapies (acupuncture, chiropractic, homoeopathy, hypnotherapy, medical herbalism, osteopathy) during 1998 with an estimated 22 million visits. It is important that those with whom they consult are properly trained, understand the limits of their competence and know when and to whom to refer. There has also been widespread concern about the safety, in particular, of traditional Chinese medicines when inappropriately administered...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."

These important observations are as valid today as they were in 2008.

Summary
Despite previous agreement that statutory regulation could be the only way to safeguard the public from poorly trained and unethical herbal practitioners, the government now favours voluntary accreditation by the Professional Standards Authority (PSA).

The U-turn by the government comes 15 years after statutory regulation of herbal practitioners was first recommended to the Department of Health by the prestigious House of Lords' Science and Technology Select Committee in 2000.

The recommendation also reverses an earlier decision by the Secretary of State for Health in 2011 to implement statutory regulation for herbal practitioners and is at odds with calls for statutory regulation made by two previous Department of Health Working Groups, in each case supported by an overwhelming public vote in favour of statutory regulation to ensure safe treatment by trained practitioners.

A clear majority of the working group favoured statutory regulation as evidenced by an open letter sent to the Minister signed by more than half the Working Group but the DH/MHRA has used the Working Group undemocratically and unilaterally to make recommendations with which the majority of Working Group members disagree. The majority views of this Expert Working Group were ignored and, despite assurances to the contrary, a draft of the Report was not shared with the Group before publication.

Chair of the EHTPA and member of the Herbal Practitioner and Medicines Working Group, Michael McIntyre says: "Herbal medicine is internal medicine and like other types of internal medicine practised in the UK, requires statutory regulation for those who practise it.

[11] Report to Ministers from the DH Steering Group on the Statutory Regulation of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK**.** Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_086359?IdcService=GET_FILE&dID=169241&Rendition=Web. Accessed 29/03/15.

"The only way that the public can be assured of receiving safe treatment from well trained, ethically practising herbal practitioners is via statutory regulation since voluntary accreditation leaves the public open to poor practice from ill-trained practitioners who have opted out of, or never signed up to the voluntary scheme in the first instance."

Not only will voluntary regulation under the PSA fail to ensure the public are consulting trained and ethical practitioners, it will also fall short of ensuring herbs supplied by herbalists are sourced from companies with adequate quality assurance systems, leading to cheaper supplies of inferior and suspect quality.

Dr Dick Middleton, Chairman of the British Herbal Medicine Association (BHMA) commented: "The proposals will not prevent the continued availability of low quality or adulterated herbal supplies to herbal practitioners for use in their practice. Herbal practitioners will be unable to identify high quality herbal material and this will inevitably lead to a continued and unacceptable risk to patient safety."

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Appendix A
Evidence-based herbal medicine?

Herbal/traditional medicine has for the most part been practised for hundreds, even thousands of years – a feature which needs to be considered when it comes to building an evidence base. This is recognised in the *European Directive on Traditional Herbal Medicinal Products (2004/24/EC)* which notes *that "The long tradition of the medicinal product makes it possible to reduce the need for clinical trials insofar as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience."*

Given that traditional use is recognised by the EU as sufficient to justify the widespread sale and use of OTC herbal medicines via the THMPD, it seems inconsistent that the Report from the Deputy Chief Medical Officer of Health for England demands that the parallel use of herbal medicines by herbal practitioners will *"require the embracing of a research culture where treatments are properly tested for safety and effectiveness in high quality studies."* His view is that *"the majority of herbal medicine is not supported by good quality evidence"* and that *"herbal medicine practice is therefore based on traditional practice rather than science."* But is this so? There are many thousands of scientific papers published on the medicinal possibilities and potential of herbal medicines to treat a wide variety of diseases ranging from minor self limiting conditions to cancer and autoimmune diseases which constitutes a remarkable body of evidence. The fact that this may not be presented in RCTs should not be used to invalidate this extraordinary corpus of knowledge.

A 2008 editorial from the *BMJ* Journal *Evidence Based Medicine*[12] drew attention to a clear double standard which sees CAM therapies under fire for lack of evidence, contrasting this to

[12] Barnett H, Iheanacho I. Editorial in *BMJ Evidence Based Medicine* –August 28th, 2008.

the way conventional medicine is incorrectly portrayed as being largely supported by a secure evidence base.

> "Is the concept of evidence-based medicine flexible enough? In particular, can it embrace interventions for which there is a long history of use, but a lack of hard research data? It should do, according to a famous definition published 12 years ago in which evidence-based medicine (EBM) was portrayed as 'the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients'. This definition made allowances for missing or inappropriate evidence, and, crucially, required the application of clinical judgment and recognition of patient values. Today, however, there is a common, rigid mindset that equates EBM solely with the conclusions of randomised controlled trials and systematic reviews of these studies, to the exclusion of other 'best evidence' and the needs of individual patients. This simplistic thinking is being increasingly challenged by new moves to enhance the status of older, under-researched treatments: for example, the registration of herbal medicinal products by the UK Medicines and Healthcare products Regulatory Agency (MHRA).
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> When it comes to older treatments, there is often a gap between empirical evidence, clinical practice, and patient experience. Moreover, there are conspicuous double standards in attitudes to older treatments. For example, about half of all so-called conventional healthcare interventions continue to be used even though research on their efficacy is non-existent or equivocal. By contrast, traditional complementary and alternative therapies that have been widely used for many years and continue to be popular with patients are regularly dismissed out of hand on the grounds that there is little 'scientific' evidence to confirm whether they work.
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> There are also obvious problems associated with focusing entirely on published trial literature as the supposed basis for evidence-based practice. The efficacy studies that form the backbone of EBM represent only a small part of the total research literature, and may be of limited value in assessing safety. And, of course, most efficacy research is sponsored by the pharmaceutical industry and is drug orientated. Potentially valuable traditional medicines, non-drug interventions, or other aspects of health care receive much less attention. It is dangerous to assume that concentrating exclusively on published trials and systematic reviews at least identifies those interventions that have proven their worth to clinical practice. In reality, a good look through the Cochrane Library or other research databases reveals that the interventions and questions assessed by RCTs are often far removed from the real needs of patients and their healthcare professionals. This distortion reflects not just the selectivity of the research conducted, but also positive and negative publication biases. Examples include publication biases in trials of treatment for acute stroke, and also in trials of antidepressant drugs.
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> Less obviously, and more controversially, there are questions about whether the pharmacological randomised controlled trial model for research is sufficient to assess long-established interventions. One concern is that, because many of these interventions comprise several components, the individual effects of which may be hard to isolate and measure separately (e.g. palliative care, public health, or many complementary and alternative therapies), artificially standardising them to fit a drug-trial model may involve over-simplification. This will then raise questions about the real-world applicability of the study results. Accordingly, there is an argument for a different type of research strategy for long-established interventions, with a different order of priority..."

More recent commentaries also question the view that EBM has resulted in substantial health gains for the general population. Every-Palmer and Howick suggest that EBM is failing.[13]

> "Evidence-based medicine (EBM) was announced in the early 1990s as a 'new paradigm' for improving patient care. Yet there is currently little evidence that EBM has achieved its aim. Since its introduction, health care costs have increased while there remains a lack of high-quality evidence suggesting EBM has resulted in substantial population-level health gains. In this paper we suggest that EBM's potential for improving patients' health care has been thwarted by bias in the choice of hypotheses tested, manipulation of study design and selective publication. Evidence for these flaws is clearest in industry-funded studies. We argue EBM's indiscriminate acceptance of industry-generated 'evidence' is akin to letting politicians count their own votes. Given that most intervention studies are industry funded, this is a serious problem for the

[13] Every-Palmer S(1), Howick J. How evidence-based medicine is failing due to biased trials and selective publication. .*J Eval Clin Pract.* 2014 Dec;20(6):908-14.

overall evidence base. Clinical decisions based on such evidence are likely to be misinformed, with patients given less effective, harmful or more expensive treatments. More investment in independent research is urgently required. Independent bodies, informed democratically, need to set research priorities. We also propose that evidence rating schemes are formally modified so research with conflict of interest bias is explicitly downgraded in value."

Concerns regarding hierarchies of evidence were famously explored by Professor Sir Michael Rawlins, Chairman of the National Institute for Health and Clinical Excellence (NICE) in his Harveian Oration to the Royal College of Physicians in October 2008.[14]

"The dispute about the evidential basis of modern therapeutics has become particularly apparent with the emergence, over the past 30 years, of what are known variously as 'rules', 'levels' or 'hierarchies' of evidence... Such hierarchies place randomised controlled trials (RCTs) at their summit with various forms of observational studies nestling in the foothills. They are used – as a form of shorthand – to provide some intimation of the 'strength' of the underlying evidence; and, particularly by guideline developers, to then 'grade' therapeutic recommendations on the basis of this perceived strength...

The notion that evidence can be reliably placed in hierarchies is illusory. Hierarchies place RCTs on an undeserved pedestal for, as I discuss later, although the technique has advantages it also has significant disadvantages. Observational studies too have defects but they also have merit. Decision makers need to assess and appraise all the available evidence irrespective as to whether it has been derived from RCTs or observational studies, and the strengths and weaknesses of each need to be understood if reasonable and reliable conclusions are to be drawn. Nor, in reaching these conclusions, is there any shame in accepting that judgements are required about the 'fitness for purpose' of the components of the evidence base. On the contrary, judgements are an essential ingredient of most aspects of the decision-making process....

Hierarchies attempt to replace judgement with an oversimplistic, pseudoquantitative, assessment of the quality of the available evidence. Decision makers have to incorporate judgements, as part of their appraisal of the evidence, in reaching their conclusions. Such judgements relate to the extent to which each of the components of the evidence base is 'fit for purpose'. Is it reliable? Does it appear to be generalisable? Do the intervention's benefits outweigh its harms? And so on. Decision makers have to be teleoanalysts. Although techniques such as Bayesian statistics will undoubtedly assist they will not be a substitute for judgement. As William Blake (1757–1827) observed: 'God forbid that truth should be confined to mathematical demonstration'."

A 2009 editorial on Integrative Medicine in the BMJ reflected on the conundrum facing those who wish to integrate herbal/traditional medicine into healthcare alongside mainstream medicine: [15]

"We do not currently have enough evidence to close the door on research into integrative medicine and pronounce it ineffective. However, we will not be serving the best interests of evidence informed choice simply by undertaking more, and expensive, placebo controlled trials with non-typical patients and artificially standardised interventions, and ever more systematic reviews of existing heterogeneous, underpowered, and low quality studies. Rather, we should work towards closing the evidence gap by broadening the range of evidence we use to evaluate the complex interventions that are characteristic of, although not exclusive to, integrative medicine."

Herbal/traditional medicine typically involves individualised treatments based on a complex clinical encounter. This suggests that to measure effectiveness in a meaningful way requires a specific programme of research to be developed for these therapies which combines pragmatism with scientific rigour. The recorded history of traditional use over many years should be evaluated and incorporated into the evidence base supporting the effectiveness and

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[14] Rawlins M, *De Testimonio* – 'On the evidence for decisions about the use of therapeutic interventions', *The Harveian Oration*, Royal College of Physicians, Oct 2008, ISBN 978-1-86016-347-0.

[15] MacPherson H, Peters D, Zollman C. ' Closing the evidence gap in integrative medicine', *British Medical Journal* 2009;339:b3335, doi: 10.1136/bmj.b3335 , 1 September 2009.

safety of herbal/traditional medicines and acupuncture. In addition, stakeholder needs, including those of the patient, service providers, and the practitioners, require that this corpus of knowledge is subjected to a particular scientific scrutiny that needs to combine methodological rigour with an appreciation of the complex and individualised nature of these forms of medical intervention. The funding of such research is problematical, given the fact that the pharmaceutical sector has no interest in identifying treatments that do not lead to specific drug development and that herbal medicines that grow in the fields, mountains, woods and forests cannot be patented and therefore offer no commercial advantage to drug companies.

Appendix B
The WHO traditional medicine strategy: 2014-2023[16]

The WHO traditional medicine strategy: 2014-2023 observes that Traditional Medicine (TM) is an important and often underestimated part of health services. WHO highlights the long history of use of TM a in health maintenance and in disease prevention and treatment, particularly for chronic disease. The WHO specifically recommends:

- The integration of TM within national health care systems, where feasible, by developing and implementing national TM policies and programmes.
- Promoting the safety, efficacy and quality of TM by expanding the knowledge base, and providing guidance on regulatory and quality assurance standards.
- Increasing the availability and affordability of TM, with an emphasis on access for poor populations.
- Promoting therapeutically sound use of appropriate TM by practitioners and consumers.

The WHO places a strong emphasis on quality, safety and regulation. Despite years of detailed work by three prestigious committees, the UK has as yet failed to establish statutory regulation for herbal practitioners in spite of that being the clear wish of UK citizens expressed in two UK wide public consultations.

Herbal medicine in the hands of qualified, well regulated practitioners has significant potential to contribute to public health e.g. by reducing antibiotic prescribing and by helping combat and the huge problem of antimicrobial resistance. Because of the lack of statutory regulation, the public are accessing from the internet herbal medicines that they cannot obtain from qualified practitioners. This clearly demonstrates the shortcomings of existing regulation.

We urge the incoming government to implement statutory regulation of herbal practitioners and to introduce the legislative means to make available the herbal medicines that they require. To do otherwise is to fail the needs of the millions of UK herbal citizens who consult herbal practitioners.

[16] http://www.who.int/medicines/publications/traditional/trm_strategy14_23/en/