**Response from Michael McIntyre, Chair, European Herbal and Traditional Medicine Practitioners Association to** "*Items which should not be routinely prescribed in primary care: A Consultation on guidance for CCGs*" see

*https://www.engage.england.nhs.uk/consultation/items-routinely-prescribed/*

**Herbal medicines –long-term safe use**

The statement that the MHRA allows herbal products to be marketed for minor health conditions that does not require medical supervision is consequent on European Directive 2004/24/EC.

This states that:

> "The long tradition of the medicinal product makes it possible to reduce the need for clinical trials, in so far as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience. Pre-clinical tests do not seem necessary, where the medicinal product on the basis of the information on its traditional use proves not to be harmful in specified conditions of use."

This Directive makes it clear that the efficacy of the herbal product is plausible *on the basis of long-standing use and years of clinical experience*. The notion that there is lack of robust evidence for use for herbal medicines flies in the face of this important concept ignoring many years of clinical experience, relying solely on hugely expensive clinical trials to validate all treatments that should be made available. Such trials are unlikely to be undertaken since herbal medicines, growing naturally and not being synthesised in a laboratory, cannot be patented to make a return on the substantial investment involved. It costs billions to develop a new drug, and drug manufacturers require a return on their investment. Studies show that estimates of bringing a new drug to the market range from approximately $160 million to $2 billion (https://www.drugwatch.com/manufacturer/clinical-trials-and-hidden-data/). This is a profound institutional bias that threatens to annihilate access to plant medicines that have been the source of modern conventional medicine itself.[1]

**Herbal medicine is cost effective & meets the needs of 'effectiveness gaps'.**

It is widely acknowledged that NHS is struggling to meet the financial burden of providing medicines that are becoming ever more expensive. At the same time, conventional medicine is recognising a number of significant therapeutic effectiveness gaps i.e. areas of clinical practice in which available treatments are not fully effective. Long-term conditions such as arthritis, chronic migraine, depression and insomnia are some examples of illnesses that are generally poorly managed by pharmaceuticals. Another important area where conventional medicines are now proving increasingly ineffective is in meeting the growing menace of antimicrobial resistance. Prohibiting the prescription of herbal medicines will close down an important way that the herbal medicine can help the NHS on both these fronts, economic and

[1] Fabricant D S, Farnsworth N R. The value of plants used in traditional medicine for drug discovery.*Environ Health Perspect*. 2001 Mar; 109(Suppl 1): 69–75

therapeutic. Herbal medicines are considerably less expensive to produce than their conventional counterparts and could save the NHS considerable sums of money if they were more frequently prescribed as there is evidence that herbal medicines can alleviate a range of common conditions that characterise the aforementioned effectiveness gaps such as arthritis, depression and insomnia as well as sparing the use of conventional antibiotics and/ or enabling antibiotics to overcome bacterial resistance.

An investigation into the potential contribution of complementary therapies to healthcare in the UK by the economist Christopher Smallwood (*The Role of Complementary and Alternative Medicine in the NHS 2005*)[2] noted:

> "In 2004 the NHS spent £40 million on antidepressant drugs (*note that by 2016 this figure had risen to £266.6 million*[3]) at an average net ingredient cost of £13.82 per prescription. Compared with this a weekly course of St John's wort costs just 82p. Similarly non-steroidal anti-inflammatory drugs accounted for £247 million in 2004 at an average net ingredient cost of $13.82 per prescription. Phytodolor (*a commercially available herbal product*) costs just 45p a week. The cost savings cannot be ignored."

A 2011 meta-analysis of Phytodolor containing three well-known anti-inflammatory plant extracts"demonstrated a better pain reduction than placebo in patients with pain due to musculoskeletal disorders, probably equivalent to NSAIDs, and was well tolerated."[4]

Since Smallwood published his review, randomised clinical trials on St John's wort (*Hypericum perforatum*) show that extracts are "more effective than placebo and similarly effective as standard antidepressants while having better tolerability in the acute treatment of major depressive episodes."[5] A paper published by the European Herbal and Traditional Medicine Practitioners Association shows the benefit of using herbal medicines to spare the use of antibiotics as well as to reactivate conventional antibiotics to which bacteria have become resistant. [6] This is not the time for the NHS to contemplate the wholesale abandonment of herbal medicine that has significant potential to meet the needs of patients in the 21st century.

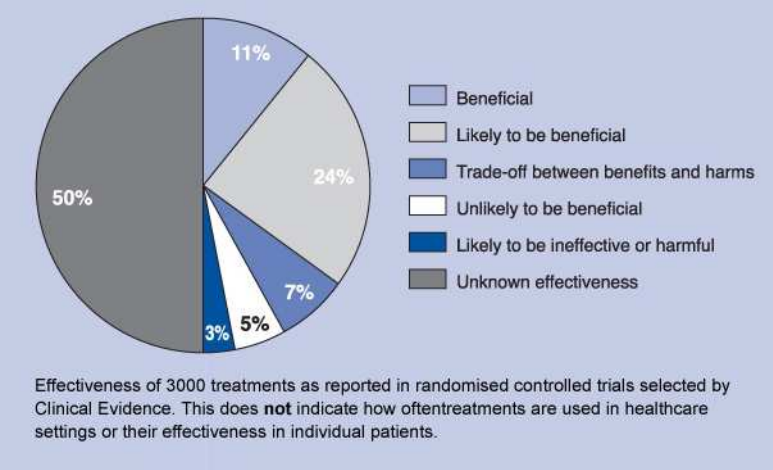
**Evidence base – double standards**

The proposed restriction of herbal medicines by the NHS should be seen in the context of a lack of evidence for many conventional medicines routinely prescribed to patients on the NHS. This is illustrated by an ongoing study published by the BMJ Journal *Evidence Based Medicine*.

*Evidence Based Medicine* selects around 3000 treatments that have subject to research analysis and divides their effectiveness for specific indications into categories. The Journal regularly updates this data noting that it devotes considerable time on this assessment, calling

[2] http://www.richardeaton.co.uk/wp-content/uploads/2017/06/smallwood-report.pdf
[3] https://www.theguardian.com/society/2017/jun/29/nhs-prescribed-record-number-of-antidepressants-last-year
[4] Uehleke B, Brignoli R, Rostock M, Saller R, Melzer J. Phytodolor® in musculoskeletal disorders: re-analysis and meta-analysis. *Forsch Komplementmed.* 2011;18(5):249-56
[5] Linde K. St. John's wort - an overview. *Forsch Komplementmed*. 2009 Jun;16(3):146-55.
[6] Available at http://ehtpa.eu/research/index.html

on the knowledge of information specialists, editors, peer reviewers and expert authors, and revisiting its categorisations at each update. Its current on-line review[7] is displayed below.



Effectiveness of 3000 treatments as reported in randomised controlled trials selected by Clinical Evidence. This does **not** indicate how oftentreatments are used in healthcare settings or their effectiveness in individual patients.

This pie chart shows that of the 3000 treatments only 11% are rated as beneficial, 24% likely to be beneficial, 7% as trade off between benefits and harms, 5% unlikely to be beneficial, 3% likely to be ineffective or harmful, and 50%, the largest proportion, as having unknown effectiveness. **These figures suggest that most decisions about treatments within conventional medical practice still rest on the individual judgements of clinicians and patients.**

An editorial in a previous edition of *Evidence Based Medicine* draws attention to a clear double standard which sees CAM therapies under fire for lack of evidence and contrasts this to 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).
>
> 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

[7] http://clinicalevidence.bmj.com/x/set/static/cms/efficacy-categorisations.html. Accessed 3/9/17

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.

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.

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..." [8]

There is growing unease, referred to in this editorial, about the appropriateness of much conventional research to provide EBM. This concern was explored by Professor Sir Michael Rawlins, currently Chairman of the Medicines and Healthcare products Regulatory Agency (MHRA), in his Harveian Oration to the Royal College of Physicians in October 2008.[9]

"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

[8] Barnett H, Iheanacho I. Editorial in *BMJ Evidence Based Medicine* –August 28th, 2008.
[9] 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.

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'."

## The demand for herbal medicine

Herbal medicine is in considerable demand. Imposing a wholesale embargo on its prescription means that patient choice will be severely restricted. Millions of UK citizens regularly make use of herbal medicines. Research by Ipsos MORI (November 2008) for the Medicines and Healthcare products Regulatory Agency (MHRA) reported that:

- more than a quarter of the population had bought over the counter herbal medicines at least once in the previous two years
- around one in twelve had consulted a practitioner of Western herbal medicine
- around one in twenty had consulted a practitioner of traditional Chinese Medicine[10]

The popularity and widespread use of herbal medicines is further demonstrated by data provided by an NHS publication (published 2016) *Equality and Health Inequalities – Full Analysis - Items which should not be routinely prescribed in primary care* see https://www.engage.england.nhs.uk/consultation/items-routinely-prescribed/supporting_documents/ehiimpactitemsnotroutinelyprescribedprimarycare.pdf (2017)

This demonstrates use of herbal medicine for the young (19.3%) and old (44.5%) alike.

**Prescriptions of Part A herbal medicines dispensed Jan - Dec 2016**

Number of patients — Percentage of patients

| Under 18 | 18 to 30 | 31 to 44 | 45 to 64 | 65 and over | Total | Under 18 | 18 to 30 | 31 to 44 | 45 to 64 | 65 and over |
|---|---|---|---|---|---|---|---|---|---|---|
| 584 | 145 | 261 | 689 | 1,344 | 3,023 | 19.3% | 4.8% | 8.6% | 22.8% | 44.5% |

## Conclusion

Instead of deprescribing herbal medicines, the NHS should be making use of this extraordinary resource that can both save money and meet the unanswered needs of many patients. If herbal medicines are not appropriately available on the NHS, this will undoubtedly contribute to the soaring cost of medication that threatens the integrity and purpose of the NHS.

[10] https://www.gov.uk/drug-safety-update/public-perception-of-herbal-medicines. Accessed 1/9/2017