

# The Regulation of Herbal Medicine in the UK and Europe. An Interview with Michael McIntyre - Chair of EHPA

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## What is the history of the European Herbal Practitioners Association (EHPA)'s involvement in herbal regulation in the UK and Europe?

In the early 1990's, it became clear the European Union was going to have a major impact on herbal regulation in the UK and EU. In 1992, I came across a document published by the European Committee on Proprietary Medicinal Products (CPMP) listing some 30 herbal remedies which were described as having "serious risks without any accepted benefit". To my astonishment, several herbs on the list were being used daily in herbal practice and, properly used, are in my opinion not at all unsafe. For example, the list contained parsley seed – a common ingredient in food. Also on this list was *Berberis Vulgaris* because it contained the alkaloid; berberine. This list had serious implications for Chinese medicine as well as western herbal medicine, as several Chinese herbs such as Huang Lian (*Coptis chinensis*) contain this alkaloid and could not be used. Unbelievably, despite vigorous protests from the EHPA, this 1992 list was recently readopted by the Herbal Medicinal Products Committee within the European Medicines Agency in 2005. Back in 1992, I realised there was going to be a problem and I was aware that if we were to be able to continue being able to use medicinal herbs, all those using them should work together to safeguard the legislative basis for our practice. It rapidly became clear that in the UK this could only be achieved by the dual strategy of gaining statutory regulation for practitioners (which would allow us to be legally differentiated from ordinary members of the public) and reforming Sections 12 and 56 of the Medicines Act of 1968, which governed the supply and sale of herbal medicines in the UK.

In 1947, The Minister of Health; Aneurin Bevan, had offered UK herbalists the opportunity of being included within the NHS (the UK National Health Service), but they were too disunited to present a unified profession and so the opportunity was lost. Now as Britain is a multi-cultural society, I thought

that we needed to represent traditional herbal medicine in its different forms. From the very outset, when I founded the EHPA in 1993, we sought to represent Western and Chinese herbal organisations, as well as Ayurvedic, Tibetan and Japanese medicine organisations. We also asked UK representatives of Unani Tibb to join us, but this has not happened to date.

The founding of the EHPA came not a moment too soon as in 1994, there was suddenly a disastrous threat to herbal medicine in the UK. The UK government signed up to a European Directive governing all medicines. The idea was that every medicine in Europe had to have a licence. We knew nothing of this and only discovered it was actually happening at the point of signature. We were told that every herb, whether it was Chinese, Western or Ayurvedic would have to have a full medicine licence. People often ask why herbs shouldn't have a full licence as they are medicines. But there are a number of problems with this notion. Herbs are generic; they can grow in people's back gardens and so cannot be patented. For this reason no company could recoup the huge sums of money required to license a herb. In addition, the licensing requirements require the active constituents in the remedy are precisely identified, which is not usually possible when it comes to a herbal remedy containing an orchestra of chemicals. The requirement for all herbs to be licensed therefore would have amounted to a complete ban on herbal medicine in the UK.

When the MCA (now the MRHA) said there could be no change in policy, we contacted the main national newspapers and the Today programme and in a short space of time we had the most incredible publicity for our cause. We were most generously helped by Paul McCartney who lent us the expertise of his P.R. Company, completely free. John Major, Prime Minister at the time, already in difficulty because his Eurosceptic back benchers soon became alarmed at how much damage the adverse publicity about the "herbal ban" was doing to his government. Thousands of letters were written to the government, MEPs and

MPs by angry members of the public complaining about the threat to herbs. As soon as the Prime Minister became personally involved, Government lawyers managed to find a way to patch up the legislation to relieve the immediate threat to herbal medicine. They did this by saying that herbal medicines were not industrially produced but traditionally produced and therefore not subject to the main EU Medicines Directive. The phrase 'industrially produced' was within the definition of medicine of the main European medicines directive 2001/83/EC (previously called Directive 65/65/EU).

This agreement was achieved just a few days before Christmas in 2004 and everyone claimed a victory. Shortly afterwards, I received a call from a senior civil servant at the MHRA saying that we had a significant problem with this patched-up legislation. He said that were the herbal legal "solution" to be challenged in a European court, it probably would not stand up to scrutiny. In short, new legislation was needed. Part of the drive to get statutory regulation has always been about finding a firm legislative foundation for herbal medicines. This, for reasons explained below, requires those using herbs are legally recognised to be able to prescribe herbal medicines.

The Medicines Act of 1968 was enacted, following another crisis over drug Thalidomide given to pregnant women to stop morning sickness. At the time there was no proper licensing system for any medicines, so the government rushed legislation through to require all medicines to be licensed. In 1967, the western herbal practitioner, Fred Fletcher Hyde, realised, as we did in 1994, that the Medicines Act being proposed would outlaw any form of herbal medicine in the UK as herbal medicines would never qualify for full licences. For this reason he proposed that herbal medicines should be exempt from licensing. Thus Section 12 of the Medicines Act of 1968 allowed for herbal medicines to be exempt from licensing. A Statutory Instrument (SI 2130) further permitted powerful herbs like Ma Huang (*Ephedra Sinica*) to be used by herbalists. But the 1968 Act never defined the word herbalist. I reckon in 1968 there were no more than 50 herbalists operating in the UK so no one cared much about these exemptions or the lack of clarity about who was qualified to be a herbalist. However, today we have around 3,000 practitioners using herbs and so it's a completely different situation. In 1994, the MHRA realised that anyone could give another person a dangerous herb, as at that point, they are defined as an herbalist merely by the act of providing that herb to another person. This too made the authorities determined to reform Section 12 of the Medicines Act of 1968.

When we set up the EHPA in 1993, the UK government started talking to us about statutory regulation. At that time we thought it would only take a

few years to achieve this but in the event it has taken years and were aren't there yet. In 1995, I went to Brussels to see the head civil servant in charge of medicines and talked to him about the need to change the European medicine law to accommodate traditional medicines. He told me it wasn't possible. What made it worse was in 1990 there was a problem with the herb Fang Ji, which can be one of two herbs, Han Fang Ji (*Stephania Tetandra*) and Guang Fang Ji (*Aristolochia Fangchi*). Some doctors in Brussels who ran slimming clinics and were not trained in Chinese medicine, decided to include in their formulations various diuretics. They got hold of some Chinese information and read that Fang Ji was a diuretic. So they ordered Fang Ji in powder form from Taiwan. They didn't stipulate which Fang Ji they wanted and they got Guang Fang Ji (*Aristolochia Fangchi*) instead of Han Fang Ji (*Stephania Tetandra*). They added this to their slimming capsules along with amphetamine to shut down the appetite, Belladonna, also to reduce the urge to eat, and another conventional diuretic drug called Acetazolamide. It is also possible that the women on this dietary regime were given serotonin injections. It is now known that aristolochic acid in Guan Fang Ji (*Aristolochia Fangchi*) is nephrotoxic and it is likely that this disastrous side effect was tragically amplified by the cocktail of drugs co-administered to the poor women who undertook the slimming programme. Within two to three years the scale of mass poisoning became evident. Some 200 women in Brussels, also home to the European Commission and European Parliament, lost their kidneys. Many have now developed cancer, others have died and many will be on dialysis machines for the rest of their lives. So you can understand when I went to Brussels and started to talk about the need for user friendly legislation for herbal medicine, the European Civil Servants didn't want to know.

I came back to the UK and spoke to a friend who was a journalist about our predicament. He put me in touch with a journalist from the *Daily Express* who asked for more details. I gave him the name and phone number of the person I had been talking to in Brussels. A few days later the *Daily Express* journalist rang back and said he had a front page story as the civil servant in Brussels had stated that herbs would be banned. The *Daily Express* ran the story the next day and I noticed when I returned to Brussels the civil servants took me lot more seriously as I continued to lobby for herbal medicines to have their own herbal Directive. In the event, the Herbal Medicinal Products Committee (HPMP) in the European Medicines Agency (EMA) underwent a change of heart when it became clear that large herbal companies in Germany were going to find it difficult to continue marketing their products under existing EU legislation. Thus in 2004 we got the Traditional Medicinal Products Directive (THMPD), which provides new regulations governing over-the-counter (OTC) herbs sold direct to the public. When

this is fully implemented in the UK, this Directive will replace Section 12(2) of the Medicines Act of 1968 that also deals with the OTC herbal sector.

Sadly, despite our best efforts, there are problems with the THMPD. Conventional medicines need to prove safety and efficacy to qualify for a medicines licence (marketing authorisation). Evidence of efficacy can only be obtained by double-blind clinical trials or significant published scientific data. As explained the costs involved in this are so great that no herbs would be licensed using this route. The European Commission recognised this problem and decided that herbal medicines could prove efficacy based upon tradition. To qualify for a THMPD licence a herbal product has now to demonstrate 30 years of traditional use with 15 years of this being in Europe. As it happens, in 1986, I started the first Chinese herbal import company in the UK and so in the process guaranteed that the majority of herbs have been used in Europe for more than 15 years. But for new herbs, a THMPD licence will be a problem. There is another problem with the THMPD and this concerns the Quality Control Guidelines that were accepted (despite our opposition) after the Directive became law. These guidelines demand that there is a constant monitoring of markers for all herbs used a product from start to finish of the production process. In this way, the manufacturer is required to demonstrate in the end product that there is the same percentage of markers present as there were at the beginning of the processing. Whilst this is possible for single herb products, it becomes extremely difficult to achieve for multi-herb compounds (such as Chinese traditional formulations) When performing chromatography, some herbal chromatographs can obscure others with which they are combined. In practice you often can't 'see' the markers for all the herbs in the formulation because the 'fingerprint' of some herbs is so strong.

In trying to get something done about this we have been extremely fortunate in having the active support of the Prince of Wales. The Prince was able to talk to Europe when we weren't getting anywhere and organise a meeting with Dr Keller, the head of the EU HMPC. As a result of all this lobbying we have recently managed to persuade the EMEA to review the Quality Control Guidelines for multi herb compounds. The EMEA has recently published a concept paper on this subject, which is out for consultation until November this year. But if we are to achieve our goal of having workable legislation across Europe, we still have much work to do. We cannot afford to let up for a moment!

As explained, the THMPD is designed to licence traditional medicines to be sold OTC direct to the public without any practitioner intervention. For this reason, it is not really suitable for the supply of most TCM patent medicines. The THMPD requires that the

product's indications are clearly displayed on the label. But how could this be done for say Liu Wei Di Huang Wan (Six-Ingredient Decoction with Rehmannia)? If one wrote that this is good for lower back pain on the packet, it would possibly lead to misuse by someone with those symptoms who actually had Kidney Yang Xu. These Chinese patent medicines need the intervention of a trained Chinese doctor to look at the tongue, the pulse and read the symptoms and determine the pattern of disharmony. An untrained patient cannot do this. For this reason, most of Chinese patent medicines are not suitable for self medication via the THMPD. Some other route is required. These products are clearly "industrially produced" so under the main EU Medicines Directive 2001/83/EC they would appear to need a licence. What could be done to ensure their continued availability? This was the question that faced us over the past four years or so.

A possible solution occurred to me some time ago and I discussed this with the MHRA. I found the main EU medicines Directive permitted "authorised health professionals" to approach a company and order for specific patients' needs particular formulations, which can be industrially produced without the need for a licence. Now, I am delighted to say, the MHRA has produced a discussion paper, proposing this route of supply. I should make it clear that under this regulation, companies will not be allowed to advertise Chinese patent medicines or put them on the market. The initiative for production has to come from practitioners themselves. In addition, the MHRA will only allow this if there is an effective quality control applied to the manufacturing process. To be able to qualify for this exemption, practitioners must be statutorily regulated otherwise they could not be considered "authorised health professionals". Lastly, I should note that in the rest of the EU where non-doctor practitioners are not being statutorily regulated, no such solution will be possible and it is likely (see below) that Chinese patents will be driven off the market.

### **When will regulation come into effect in the UK and Europe?**

When we launched the EHPA in 1993, I remember Department of Health (DH) civil servants telling me that we might be statutorily regulated by 1998-99, but we are still struggling to achieve this goal in 2006 and it looks like that it will be a few years yet before we get to it. Since 2003, we had some seven ministers and almost as many civil servants running our sector, so there has been a significant delay arising from constant changes in the Department of Health. We have had to contend with structural changes at the DH, General Elections (during which time virtually no work could take place) and finally the general review of healthcare regulation ordered by the Government, post Shipman. With the publication of the Foster report two months ago on the regulation of the "non medical health

sector”, we seem to be approaching the ‘end game’ now. The Foster Report recommends that we should not have our own Council (Acupuncture, Herbal Medicine and TCM), but that we should be attached to the Health Professions Council. I have considerable reservations about this as I fear it may lead to us losing of control of our regulatory process. In addition, the HPC requires any professions joining it to produce “evidence base” to support their particular practices. It is at least questionable whether we could provide what the HPC might require in this regard. I hope we can persuade the Government to change its mind and support the launch of a new Council as was previously envisaged by the DH itself.

### **What qualifications will be required to practice herbal medicine in the UK and Europe?**

Well in the UK, there will be a grandparenting scheme in place, so all the practitioners who are practising safely are likely to get onto the register. What is clear from both the recent Chief Medical Officers Report on the regulation of doctors and the Foster Report is that the emphasis on all healthcare workers, from doctors to all others will be on revalidation. This means all TCM practitioners, herbalists and acupuncturists will have to undergo regular revalidation and participate in mandatory continuous professional development. I submit that we should find reasons why people should be on the register rather than why they shouldn't be on it and I think this has been generally accepted. We should try and be inclusive as possible. Standards can be maintained and raised by means of revalidation and continuous professional development. As for Europe, the outlook appears less rosy as I explained below.

### **Do you think herbal medicine should have its own category in the UK or should it be mixed with acupuncture to form TCM?**

When the EPHA answered the Department of Health's consultation document in 2003, we suggested a range of titles to cover most things, for example there should be a TCM title for those that practise Chinese herbal medicine and TCM acupuncture. There should also be a title for TCM herbalist and a TCM acupuncturist and possibly there could be another title reserved for so-called Five Element acupuncturists as well. This would enable patients to know precisely what kind of treatment they were receiving and, just as important, researchers to be aware of what tradition they were researching.

### **What about the safety of herbs used in the UK and Europe?**

The MHRA has put in place the Herbal Medicines Advisory Committee (HMAC). This new body has the same ranking as the Committee of the Safety of Medicines. If any question concerning herbal safety

arises, HMAC will determine whether dry herbs are safe or not, based on current evidence. The HMAC committee is made up of people from Ayurveda, TCM, Western herbal medicine etc, as well as pharmacologists.

Prepared products (patent medicines) will be licensed by the MHRA for authorised health professionals as explained above. For dried herbs, the MHRA want to see clear systems in place so that if a herb is suddenly discovered to have been mixed up with another herb, a practitioner can access their database and see who have been prescribed that herb and warn patients to stop taking it. It is likely that the requirements to label herbal medicines will be tightened up too. The systems to ensure all this are still to be agreed.

If there is one major threat to the progress of UK Statutory Regulation of TCM, it is the constant stream of horror stories in the media about Chinese patent medicines and the fraudulent or irresponsible practice of some TCM outlets in the UK. Over the years, there has sadly been continuing bad publicity about Chinese patent medicines supplied to patients containing heavy metals such as arsenic, mercury and lead or illegally adulterated with western medicines. Further cases of kidney damage have been recorded in the UK because of the illegal supply of Mu Tong and Fang Ji, both of which are banned in the UK in all forms because of the lack of quality control to prevent herbs containing aristolochic acid being mistakenly supplied. In addition, a number of UK TCM business chains have recently been successfully prosecuted for making outrageous claims in their advertising to be able to treat “bird flu”, HIV and AIDS and cancer as well as for claiming that Chinese medicines are free from side effects. Details of all this can be accessed on the MHRA website and it does not make comfortable reading for anyone who values TCM!

### **Do you see the use of animal and mineral products in the future?**

The Herbal Medicines Regulatory Group (on which I served), was set up by the Department of Health, recommended in 2003 that any traditional product which can demonstrate safe use and is safe to consume, should be included in section 12 (1). The MHRA is now considering whether to accept this general principle. However, the MHRA has pointed out that many animal products present a TSE or viral risk, so the list of permitted substances is likely to be limited.

### **How does the practice of herbal medicine differ in the UK and Europe?**

Other Member States don't have Section 12 of the 1968 Medicines Act and so the practice of Chinese herbal medicine is much more precarious than the UK. The Irish authorities have recently introduced a version

of Section 12 into Irish law but at the moment are not planning statutory regulation of the TCM sector so there will be problems with herbal supply in Ireland too, as herbalist will not be legally differentiated from ordinary members of the public. Many TCM suppliers have been selling Chinese herbal medicines as foods across the EU, but under the European Food Supplements Directive (FSD), which is enacted in every European Member State; it is no longer possible for the majority of Chinese herbs to be marketed as foods. With the advent of the Traditional Herbal Medicinal Products Directive, there is now no “grey area” between foods and medicines to allow the sale of medicinal herbs in many Member States. For this reason, in the rest of Europe, I think it’s going to become very difficult for some TCM and herbal practitioners to get their herbal medicines or indeed to practise at all. In some Member States, particularly France and Spain, there is a strong medical opposition to anyone practising medicine who isn’t a doctor. In other Member States such as Holland and Denmark, the authorities are more easygoing, but it is still difficult to practise. For example, a friend of mine who works as a herbalist in Denmark, asked Danish authorities the legal status of herbal medicine. He was told to study the laws that pertain to waiters at a table, because when he was giving herbs to a patient, at that point as far as the law was concerned, he was giving foods to a customer in a restaurant! This shows how perilous the position of herbal medicine is in many Member States. The EHPA has been warning colleagues across Europe about this for years, but until now few practitioners appear to have taken the threat to herbal practice seriously. I predict that this is likely to change rapidly now the THMPD and FSD are beginning to bite.

### **How will this change in the future?**

The UK has been setting the pace for other Member States in gaining a firm legal basis for the practice of TCM. I very much hope that other Member States will follow the UK’s example so that TCM can flourish across Europe. I hope we can be proud of what we have managed to achieve in the past decade in securing the future of our practice. The need for us all to work together has never been more apparent. Regulation of our sector will enable the public to choose well-trained and regulated practitioners who use herbs and herbal products with an assured quality.