



REPRESENTING PROFESSIONAL HERBALISTS FROM ALL THE TRADITIONS ACROSS EUROPE

The Lord Hunt of Kings Heath,
Parliamentary Under Secretary of State,
The Department of Health,
Richmond House,
79 Whitehall
London SW1A 2NL
17/01/2003
Dear Lord Hunt,

The proposed Directive on Traditional Herbal Medicinal Products (Amending Directive 2001/83/EC). MLX 283

The European Herbal Practitioners Association (EHPA) was formed in 1993 to bring together practitioners from different traditions of herbal medicine with the aim of achieving Statutory Self Regulation (SSR) for herbal practitioners in the UK as well as in other Member States throughout the rest of the EU. The EHPA has a broad-based UK membership acting as a forum for UK Professional Registers that represent some 1,200 herbal practitioners in the UK and Northern Ireland from the Western, Chinese and Ayurvedic traditions. It also represents herbal practitioners across the rest of the EU. A complete list of member associations is appended to the end of this letter.

As you may know, for the past ten years the EHPA and its constituent UK organisations have been working closely with the Department of Health and the Medicines Control Agency to achieve an appropriate legislative framework for both herbal practice and herbal medicines. As far as updating European medicines legislation is concerned, we were among the first organisations in Europe to call for a new Directive specifically designed to regulate traditional medicines. In 1995, I led an EHPA delegation that met with the then head of DG111 (the Enterprise Directive), Mr Duboisier and his deputy Mr Brunet at the Commission seeking such an initiative. In 1999, we published an updated version of our 1995 position paper entitled "*Alternative licensing for herbal medicine-like products in the European Union*" that called for new and appropriate EU legislation for herbal medicines. In parallel with this, we have been working for several years with the Department of Health and more recently since the beginning of 2002 with the Herbal Medicines Regulatory Working Group under the Chairmanship of Professor Pittilo, mapping out the process of SSR for UK herbal practitioners.

I am writing to you now to reiterate our broad support for the proposed Directive on Traditional Herbal Medicinal Products (DTHMP). As I have explained, for a number of years the EHPA has had the view that existing European medicines legislation is inadequate to ensure the quality and safety of herbal medicines. Last July, we learnt that the Food Standard Agency sampled 543 different over-the-counter herbal products from a variety of companies and found that 42% were illegally irradiated. This was further example in a long list of poor quality products found on the market. Other significant problems that have been identified are contamination (e.g. with heavy metals), the accidental inclusion of the wrong herb and failure to give adequate safety information. This is an international problem and it is understandable that the EU is determined to regulate this "grey area".

The proposed Directive is very much in line with recommendations made by the cross-party House of Lords Science and Technology Committee. Its report on Complementary and Alternative Medicines (Nov 2000), compiled after taking evidence from a wide range of sources, was clear on the public health case for regulation of herbal remedies stating "We are concerned about the safety implications of an unregulated herbal sector and we urge that all legislative avenues be explored to ensure better control of this unregulated sector in the interests of the public health."

It has also been evident that the arrangement made in 1994 by the UK Government to classify herbal medicines as "traditionally" rather than "industrially produced" so that herbal medicines could continue to enjoy exemption granted by the 1968 Medicines Act from the need for full licensing (required by EU Directive 2001/83/EC), was unlikely to survive any legal challenge as in reality many herbal products would seem to be industrially produced.

For these reasons, the EHPA now supports the proposed DTHMP recognising that it represents the best chance to safeguard the public by ensuring reliable quality and safety standards for herbal products. In our judgement, failure of the proposed DTHMP to pass into law could potentially jeopardise the supply of herbal medicines to the public since in the absence of agreed quality and safety standards for herbal medicines throughout the EU, there would undoubtedly be a loss of confidence in the sector.

We applaud the fact that the MCA has worked hard in negotiations to make the Directive as flexible as possible. We understand from the European Commission that the next draft of the proposal, due out in the next few weeks, will give the proposed European herbals committee the powers, in individual cases, to reduce the minimum requirement for companies to demonstrate that the remedy has at least 15 years of use in the European Union. If agreed, this would represent real progress since the UK has argued right from the start that valid evidence of traditional use from outside the EU should be recognised. We also appreciate that combination products can be included within the scope of the Directive (which is unlikely to be fully implemented before 2009) and that evidence of professional herbal practitioner use of a herbal remedy will be counted as evidence of traditional use. Taken together we are satisfied that these measures will ensure that practically all herbal products currently on sale on the UK market can qualify for traditional registration.

We also understand that the updated proposals will specifically permit herbal/nutrient combination products. This would permit the addition of non-herbal ingredients, such as vitamins and minerals, to traditional herbal remedies. This would meet the concerns raised by many in the UK herbal sector and would allow a substantial extension in consumer choice. Currently such products would require a full marketing authorisation.

Understandably, we still have a few concerns about the proposed Directive in the detail of its implementation. In particular, we hope that the licensing procedure and fee for traditional registration will not turn out to be too onerous for small or medium sized herb companies to bear. Whilst we certainly agree that herbal products should be subject to quality control, we hope that you will recognise that herbal medicines are essentially different from conventional pharmaceuticals and their manufacture and production should be assured in such a way as to support traditional extraction and manufacturing processes. For example, we submit that the adoption of standards that would require subjecting plant materials to radiation or chemical intervention must be avoided. We also ask that paperwork and red tape be kept to a minimum and that the GMP standards are spelt out as soon as possible so that companies can see what measures they need to take to comply with the Directive. Again, we ask that the cost of such measures should be minimised.

Lastly, we note that Amendment 6 and 9 include the phrases "pharmacologically active levels" and "active ingredients at pharmacological level". These proposed additions to the text of the Directive raise important questions e.g. what about all those herbs where current pharmacological evidence is contradictory? We would like to see these particular amendments omitted from the final text of the Directive.

With these caveats in mind, I would like to repeat that we are broadly in favour of the proposed DTHMP and the EHPA looks forward to working with you and the MCA to see its flexible and pragmatic implementation in the UK.\

Yours sincerely,
Michael McIntyre
Chairman EHPA

Full member organisations of the EHPA:

Association of Master Herbalists
Ayurvedic Medicine Association UK
British Society of Chinese Medicine
College of Practitioners of Phytotherapy
International Register of Consultant Herbalists
National Institute of Medical Herbalists
Register of Chinese Herbal Medicine
Unified Register of Herbal Practitioners

Those organisations with associate status are:

Danish Herbal Medicine Association
Dutch Association of Acupuncture
Irish Herbal Practitioners Association
Norwegian Acupuncture Association
Swedish Herbal Medicine Association
Tara Institute of Tibetan Medicine
Copy to Dr Liam Fox, Shadow Secretary for Health
Mr Richard Woodfield, MCA