

The Rt Hon Lord Mandelson
Secretary of State for Business, Innovation & Skills
& President of the Board of Trade
Ministerial Correspondence Unit
Department for Business, Innovation & Skills

1 Victoria Street
London SW1H 0ET

04/01/2010

Dear Lord Mandelson,

The Statutory Regulation of herbal practitioners in the UK and its regulatory impact implications

I write to you in my capacity as chair of the European Herbal and Traditional Medicine Practitioners Association (EHTPA) which represents some 2,500 practitioners of herbal medicine working in the UK. These are generally small enterprises which themselves rely on the support of around 60 -80 other small to medium enterprises in the form of herbal manufacturers and suppliers. The future of many of these businesses is now in doubt because of the Government's tardy move towards the statutory regulation of herbal practitioners - something which the Department of Health has been publically committed to for many years.

As you no doubt know, The Department of Health Recently consulted on the proposed statutory regulation (closing date Nov 16 09) of herbal/traditional medicine, TCM and acupuncture practitioners.

This matter has been under consideration for a decade since the call in 2000 from the House of Lords' Select Committee on Science and Technology for the statutory regulation of practitioners of herbal medicine and acupuncture. The Government itself backed statutory regulation of this sector in 2001 and more recently key regulatory bodies, the Health Professions Council (HPC) and the Medicines and Healthcare products Regulatory Agency (MHRA) have both concluded that, like the osteopaths and chiropractors, acupuncture and herbal medicine practitioners should be subject to statutory regulation. As recently as 2006 the DH website recorded that "The Government is committed to the statutory regulation of herbal medicine, acupuncture and traditional Chinese medicine practitioners." [2][1]

Over the past eight years the DH has initiated three working groups to look at implementing this policy. All three working parties strongly supported the aim of statutory regulation of this sector. In

2005, the DH ran a public consultation on the statutory regulation of herbal medicine and acupuncture. This registered a 98% response in favour of statutory regulation. As a consequence the DH published a timetable for the statutory regulation of this sector with a section 60 order (the legal process to bring this about) to be published later that year. This timetable has not been adhered to. The Government says it will make a decision on this matter but continues to delay. As explained below, if statutory regulation does not go ahead with immediate effect, there will be a significant loss of consumer choice and huge damage to many small and medium sized businesses across the herbal supply and manufacturing sector as well as to many herbal practices throughout the UK. It is clear that in not making a decision, the Government is effectively undermining herbal medicine practice in this country.

If statutory regulation fails to go ahead there will be a loss of a wide range of herbal medicines currently supplied by manufacturers and suppliers to practitioners. Full implementation of the new European Traditional Herbal Medicine Directive in April 2011 will see the end of Section 12(2) of the Medicines Act of 1968 and with it the right of practitioners to access finished medicines from manufacturers and herbal suppliers for prescription to individual patients. This includes all finished products such as medicinal herbal pills, tablets, capsules, dried herb mixtures and medicinal herbal ointments made up for individual patients by third-party suppliers. Also under threat are third-party herbal prescription services that supply individualised herbal prescriptions (including those comprising tinctures and dried herbs) to named patients at the practitioner's request. Over the past 40 years this mode of supply has become an essential part of herbal practice in the UK and many practitioners are totally reliant on such services. All that will remain will be herbal medicines prepared by practitioners from their own premises.

Herbal medicine is extraordinarily popular. According to an Ipsos MORI report commissioned by the MHRA (January 2009), 35% of adults in the UK have used a herbal medicine whilst 26% of adults in the UK have used a herbal medicine in the past two years. This report also found that 77% of adults agree it is important that herbal medicines are regulated, with this figure rising to 87% among regular users of herbal medicines (defined as those who have used a herbal medicine within the last 2 years).[3][2]

From April 2011 the ability to order medicinal products from suppliers for individual patients is only available to statutory regulated health professionals. Without statutory regulation, from this time onwards, many patients will be unable to obtain their usual medicines. The loss of this facility will put many practitioners and several of their suppliers out of business. This will further damage the UK economy and swell unemployment during the current economic downturn. To illustrate what will happen, I enclose the results of a survey we have carried out on regulatory impact on the herbal sector if statutory regulation does not go ahead. Frankly, the results make alarming reading.

The MHRA has proposed that third-party medicines supplied on request of statutorily regulated practitioners for individual patients can continue under MHRA licence via Section 5.1 of the main European Medicines Act 2001/83/EC[4][3]. The key point here is that this facility is only available to statutory regulated health professionals.

In short, if herbal practitioners were to secure 'authorized health care professional' status through statutory regulation, they could legally commission herbal medicines from manufacturers for supply to their patients. These would have to be made to assured medicinal quality. The statutorily

registered herbal practitioner would ensure high standards in the supply of the many useful traditional medicines for the benefit of patients. Their businesses would be secured and the public will have a professional group able to deliver expert herbal treatment tailored to the individual. Herbalists will be a source of information and education about the use of herbal and traditional remedies.

I write to you now, to ask if you will intercede with the DH to impress on its Ministers the need to determine that herbal practitioners in the UK should be statutorily regulated as soon as possible otherwise the financial viability of many SMEs throughout the country will be put at significant risk.

As I am writing to you in your capacity as Business Secretary, this letter has emphasised the negative impact on SME's of Government's failure to statutorily regulate herbal medicine practitioners. However, that is not to lose sight of the vitally important fact that in the interests of patient safety, it is essential that statutory regulation is achieved. This matter has been debated enough; we need to get on with it!

I look forward to hearing from you.

Michael McIntyre

Chair EHTPA