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Dear Mr Lansley,

Re: Directive on Traditional Herbal Medicinal Products

I am writing regarding the regulation of herbal medicines in the UK, as a scientist who has been involved with ensuring the quality and safety of herbal medicines and natural products for over 30 years.

As you will be aware, a Directive on Traditional Herbal Medicinal Products came into force on May 1st 2011, with the intention of creating a harmonised licensing system for traditional herbal medicines, ensuring that patients everywhere can buy products of good quality and that they will receive accurate and reliable information about these products, including their possible interaction with other medicines. I am now concerned that some manufacturers of herbal medicines may not be complying with the Directive and, as a result, may be putting patient safety at risk.

The Directive compels manufacturers of herbal medicines to register any products intended for sale in the UK under the Traditional Herbal Registration (THR) Scheme. To achieve THR, a product must demonstrate a history of traditional use of at least 30 years, ongoing evidence of safety, adherence to Good Manufacturing Practice standards, and provision of appropriate information to users. It can then be marketed for minor medical conditions deemed suitable for self treatment.

The MHRA was one of the main champions of the Directive, believing that it would lead to the responsible manufacture of herbal products in a notoriously unregulated market. Furthermore, the British Pharmacopoeia Commission, of which I am a member, established a programme of work to produce monographs for the quality assurance of herbal medicines to support the legislation. However, it has become apparent in recent months that some manufacturers of herbal medicines are simply ignoring the Directive and are continuing to sell their products unlicensed, often by reclassifying their products as food supplements. If this practice continues, poor-quality herbal products with demonstrable health risks and inadequate safety information will continue to be sold in the UK.

Professor Helen Osborn, Head of Pharmacy & Director of Pharmaceutical Chemistry
Professor Elizabeth Williamson, Director of Clinical Pharmacy
Dr Marcus Rattray, Director of Pharmacology and Therapeutics
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This is a major concern. Food supplements are not the same as herbal medicinal products. St John's Wort, for example, has been found to interact with prescription medicines, causing a lack of efficacy in anti-HIV and anti-cancer drugs, immunosuppressants (used after organ transplantation) and even the contraceptive pill. Several Chinese medicines have persistently been found to contain *Aristolochia*, a herb linked with kidney disease and cancer of the bladder, which has been the cause of several deaths in Belgium. In total, the MHRA has issued more than two dozen safety alerts over unregulated herbal medicines in the past three years, mostly related to problems of quality and contamination with prescription drugs and heavy metals.

There is an added complication to the issue, however, in the form of the European Court of Justice (ECJ). The ECJ, over the past couple of years, has cast doubt over the legality of the Directive by questioning the extent to which a product can be described as a medicine, rather than a simple food supplement. This may explain the MHRA's reluctance to enforce the Directive effectively, if there are concerns that manufacturers of herbal medicines would be able to take legal action against it.

For example, under a judgement made on 15 January 2009 (Case C-140/07), a product cannot be regarded as medicinal where it is *"incapable of appreciably restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action. The capacity to restore, correct or modify physiological functions should not lead to the classification as medicinal products by function of products, which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions."* There have been similar judgements made by the ECJ in separate legal cases. This means that if there is no conclusive proof for the medicinal effects of a product, it would not need to be classified as a medicine, even if it has had a long historical use as a medicine and is being purchased for that reason.

However, the THMPD was established purely because this proof is lacking, because the clinical trials have not been carried out. The reason for that is quite simple: their expense, which cannot be recouped by patenting the medicine. Most herbal companies in the UK are small, so it is particularly unfair that those responsible SMEs who were encouraged by the MHRA to invest heavily in complying with the new Directive now find their businesses under threat.

I do not understand how a European Directive, which was initially enacted in 2004 but took seven years to come into effect, can now be questioned in terms of legality by the ECJ. It has serious implications for the implementation of health policy in this country.

I look forward to hearing from you.

Yours faithfully,

Elizabeth M Williamson.