

OPEN LETTER



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Rt. Hon Andrew Lansley CBE MP
Secretary of State for Health
Department of Health
Richmond House
79 Whitehall
London SW1A 2NS

17th November 2011

Dear Minister

RE: Letter to you from Professor Elizabeth Williamson concerning the Traditional Herbal Medicinal Products Directive

I am writing with regard to recent correspondence received by your office from Professor Elizabeth Williamson, Director of Clinical Pharmacy at Reading School of Pharmacy. Professor Williamson's letter expressed her concerns over the regulation of herbal medicinal products in the UK under the terms of the European Union's Traditional Herbal Medicinal Products Directive (THMPD).

Unfortunately, it appears that Professor Williamson is poorly informed in multiple areas. She appears to have misunderstood the terms of the Directive and its implications for UK manufacturers and consumers of herbal products, the attitude and response of the UK herbal products sector to the EU legislation and the state of EU case law in relation to herbal products. We further believe that the position Professor Williamson takes in her letter raises questions over her academic independence.

We have chosen to write the present letter to you as an open letter, publishing it, along with Professor Williamson's original letter and our response to her, on the Alliance for Natural Health International's European website at www.anh-europe.org. We will also be circulating these letters via links to our eAlert subscribers. We feel strongly that many of the complications now facing different sectors of the herbal industry are the result of years of behind-closed-doors meetings and agreements between governments and companies. By ensuring transparency of the key issues, through the placement of key correspondence in the public domain, we firmly believe that a more equitable solution can be developed, that does not advantage one sector at the expense of another.

In the second paragraph of her letter to you, Professor Williamson declares that, "*Patients*

"Promoting natural and sustainable healthcare through the use of good science and good law"

everywhere can buy products of good quality...” Right at the outset, this sentence demonstrates a fundamental misunderstanding of the THMPD, since the Directive is not intended to regulate products designed for use with patients. Indeed, the Directive’s text very clearly states that it is for, *“Indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment”* (Article 16a1(a)).

In the same paragraph, she demonstrates a further misunderstanding of the THMPD’s range and scope. *“I am now concerned that some manufacturers of herbal medicines may not be complying with the Directive,”* says Professor Williamson. Firstly, the THMPD provides an optional registration system for eligible herbal products – it is not the case that all herbal medicines must comply with the Directive, since many are legally sold in the UK under well-established use provisions, full marketing authorisation or the ‘herbalists’ exemption’ enshrined in Section 12(1) of the UK Medicines Act 1968. She compounds her error on this point in the following paragraph by incorrectly stating that, *“The Directive compels manufacturers of herbal medicines to register any products intended for sale in the UK under the Traditional Herbal Registration (THR) scheme.”*

Professor Williams appears to forget that not all herbal products are medicines: think of turmeric, cinnamon, broccoli sprouts or garlic, all of which have medicinal properties but which cannot be considered medicines by virtue of the long history of use as foods. It is also incorrect of her to assume that foodstuffs, including botanical food supplements, pose a risk to public health. As you will already be aware, there are clear provisions in both UK and EU food law, in particular the Food Safety Act 1990 and Regulation (EC) No 178/2002, that make it an offence for a food operator to sell a foodstuff that poses a significant risk to public health.

Again in her second paragraph, Professor Williamson falsely imputes public health risks to herbal products: *“As a result [manufacturers who do not comply with the THMPD] may be putting patient safety at risk...if this practice continues, poor-quality herbal products with demonstrable health risks will continue to be sold in the UK.”* A dispassionate examination of the evidence reveals that most incidents of safety concerns attributed to herbal products have little or nothing to do with the herbal products themselves. Professor Williamson refers to possibly the most famous example – that of the Chinese herb *Aristolochia fangchi* – later in her letter. Belgian medical doctors inappropriately prescribed this herb as a slimming aid alongside a cocktail of drugs, and when around 135 of their patients subsequently developed irreversible kidney damage, their conditions were blamed entirely on *Aristolochia*. Since then, three separate court cases have failed to determine that *Aristolochia* was responsible for these injuries.

Professor Williamson only provides a single example, that of St John’s wort, to bolster her allegation that herbal products sold as unbranded, unregistered food supplements pose a risk to public health. In fact, where food supplement versions of this popular herb have been sold, the dosage of active ingredient has been significantly lower compared with medicinal versions, and the products include precautionary warnings.

In her discussion of product quality, it is ironic that Professor Williamson has overlooked a notable flaw in the herbal Directive. Despite the intentions of its originators, the THMPD as

currently exists does not prevent poor-quality herbal products from reaching the UK marketplace. It is perfectly possible for unscrupulous manufacturers to add biomarkers to inactive or unstable products, thereby making them appear active or stable upon laboratory testing. However it is enacted, enforcement of the THMPD cannot change a situation that is built into the very legislation being enforced.

Legal considerations arising from European Court of Justice (ECJ) rulings are, we believe, crucial to gaining a complete understanding of the THMPD's implications for the herbal products industry in the UK. Professor Williamson's understanding of the situation, however, is diametrically opposed to reality. Far from being, *"An added complication"* that, *"Cast[s] doubt over the legality of the Directive by questioning the extent to which a product can be described as a medicine"*, the ECJ rulings refreshingly attempt to provide a path to clarity on the definition of a medicinal product. As such, it is part of the solution, not part of the problem. The ECJ has ruled that a medicinal determination is only possible after weighing up a product's dosage of active ingredients, their probable pharmacological effects and the product's presentation – the totality of the product, in other words. The MHRA recognises this reasoning in its Guidance Note No. 8, *"What Is A Medicinal Product?"*, but Professor Williamson appears to propose that all herbal products should be classified as medicines.

On this last point, Professor Williamson is in agreement with certain phytopharmaceutical companies. They appear to have been spurred to secure registrations under the THMPD because of the considerable competitive advantage it would give them if food supplement products containing the same, as well as many other, herbs were forced off the market. *"Most herbal companies in the UK are small, so it is particularly unfair that those responsible [companies] who were encouraged by the MHRA to invest heavily in complying with the new Directive now find their businesses under threat."* Professor Williamson fails to mention that among the most successful companies gaining registrations in the UK are German phytopharmaceutical companies, not UK ones. These companies are considerably larger than many of the companies operating solely within the UK, including distributors of traditional herbal products associated with the longest-standing, Asian systems of medicine, such as Ayurveda and traditional Chinese medicine (TCM). On the face of it, it appears that Professor Williamson may have compromised her academic independence by choosing to side with, and promote the position of, one sector of the herbal product industry. At the same time, her attitude condemns other sectors that for a variety of reasons are unable to benefit from the THR scheme.

Professor Williamson's reasons for being so critical of herbal food supplements appear to have no substantive base, and her motive is unclear to us. However, we felt it necessary to clarify Professor Williamson's misconceptions of the regulatory situation facing herbal products in the UK.

Any action or actions that you might take arising from the concerns she has expressed would, we believe, unfairly advance the cause of a particular niche within the herbal products sector at the expense of many smaller firms, who have been manufacturing safe and effective products for years, even decades. Ultimately, as a non-governmental organisation campaigning for the right to natural health, our interest lies in ensuring the public has access to the widest possible range of safe and effective natural products, whether these are available for self-care or by prescription via a suitably qualified or

experienced practitioner. Such products need to exist not only as registered medicines, but also as foods.

We would be most grateful for a response to our concerns in due course.

Yours sincerely



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cc.

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