

## OPEN LETTER



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Professor Elizabeth M. Williamson  
Director of Clinical Pharmacy  
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Food Biosciences building  
Whiteknights, PO Box 226  
Reading RG6 6AP, United Kingdom

17<sup>th</sup> November 2011

Dear Professor Williamson

### **RE: Your letter to the Secretary of State for Health concerning the Directive on Traditional Herbal Medicinal Products**

I was passed a copy of your letter addressed to the Secretary for State for Health, Andrew Lansley. I am deeply concerned that you have given the Minister incorrect and misleading information that will not be helpful in resolving the present difficult situation for a wide range of players in the herbal industry. I am even more concerned, however, by the effects of not resolving the situation for the millions of consumers in the UK and around Europe who have relied on safe herbal products to help manage their health. As you will be aware, the safety record for herbal products is exemplary, demonstrating intrinsic safety that far exceeds that of conventional foods.

I have chosen to write the present letter to you as an open letter, publishing it, along with your own letter to the Secretary of State for Health, on the Alliance for Natural Health International's European website at [www.anh-europe.org](http://www.anh-europe.org). We will also be circulating it to subscribers to our weekly eAlerts tomorrow. At the Alliance for Natural Health (ANH), we believe that the public airing of often opposing views will ultimately lead to an outcome that benefits the majority of players. This is greatly preferable to the situation you appear to condone, where one sector is given an advantage at the expense of another. Many of the problems that now face herbal products in Europe are, I believe, the result of a lack of openness and transparency. Backroom discussions between larger vested interests and government officials appear to have been the order of the day.

Below I clarify some of the main misconceptions or inaccuracies in your letter to the Secretary of State for Health:

1. **The Directive is not intended for patients.** You stated that the Directive was drafted with the intention of: *"...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."*

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

**Clarification:** The fact is that the Directive does not aim to provide registered products for patients, who are members of the public under supervision of a health professional. The Directive quite specifically states: “...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)).

- 2. Manufacturers of herbal products are not required to comply with the Directive if their products are outside its scope and there are already safeguards in place in food law making it illegal for manufacturers to sell products that pose a risk to public health.** You indicated, “*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.*” **Clarification:** You intimate that all herbal medicines would need to comply with the Directive, when in fact the Directive provides an optional registration system for products that are eligible to it. If the products to which you refer were considered medicinal, being plant substances that were also medicinal by definition (according to the definition laid out in Directive 2001/83/EC as amended), there are two routes other than the Directive’s simplified medicinal registrations system that allow products to be sold legally. These are the ‘well established use’ and full marketing authorisation provisions in medicinal law. In addition, you will already know that products provided to patients by an herbalist following a one-to-one consultation are exempt under Section 12(1) of the Medicines Act 1968.

You also seem to imply that all herbal products are medicines. You would know only too well that there are a very wide range of foods that have physiological or even therapeutic effects on the body, this simple fact being amply demonstrated on Channel 4’s current *Food Hospital* series. Would you argue, for example, that cinnamon, turmeric, ginger and broccoli sprouts should only be sold as medicines, given that they are all used in certain instances for their therapeutic benefit? Surely not, bearing in mind their widespread use as foods or food ingredients.

Furthermore, if products are not registered as medicines, it does not mean that they pose a risk to public health. Foods must be safe if they are to be legally marketed. In fact, I was somewhat perplexed by your argument implying that herbal food supplements pose a risk to public health, given that registered medicines are easily the most toxic substances we ingest. Foods, as well as natural health products sold as food supplements, are relatively very much safer, the latter being even safer than conventional foods at typical levels of exposure. The Food Safety Act 1990 and EU law, through Regulation (EC) No 178/2002, firmly places the burden of safety on the manufacturer or supplier. Should a manufacturer or supplier be found to supply an unsafe product, the relevant government authority has the capacity to have the food or substance removed from the market and the company may be prosecuted accordingly. This has happened from time to time, albeit rarely, given the generally

high standards of safety practiced in the herbal sector.

3. **Compliance with the Directive is not compulsory for all herbal products, or even all herbal medicines.** You indicated: *“The Directive compels manufacturers of herbal medicines to register any products intended for sale in the UK under the Traditional Herbal Registration (THR) Scheme.”* **Clarification:** You have misunderstood the intent of the Directive. The Directive only provides a simplified medicinal registration scheme for products that are eligible for it. As indicated above, other pathways for legal sale of herbal medicines include the ‘herbalist’s exemption’ under Section 12(1) of the Medicines Act 1968, and medicinal registration according to well-established use or full marketing authorisation. Herbal products that are not deemed as medicines can also be legitimately sold as food supplements, where the plant materials are concentrated significantly, and as foodstuffs, where they are not.
  
4. **Where safety concerns have been identified, these have rarely been related to herbal food supplements.** You indicate: *“The Directive....may be putting patient safety at risk.”* **Clarification:** The biggest single incident that has been related to herbal exposure remains the case of the Brussels clinic where drugs and herbs, including *Aristolochia fangchi*, were prescribed as part of a slimming programme in 1990. The cocktail of drugs and herbs was prescribed by medical doctors who benefit from an exemption that allows them to prescribe unregistered medicines. Interestingly, three court cases have failed to prove that *Aristolochia* spp. were responsible for the resulting cases of renal nephritis, or the urinary bladder sarcomas that developed in a proportion of the 135 affected patients. Pharmacologists working on identifying the severe responses in these patients, all of whom received treatment over only a 3-month period when one particular protocol was administered for slimming purposes, now favour an argument that the disease was largely the result of interactions between ochratoxins present, along with use of intravenous serotonin and prescription of the now banned dexfenfluramine drug.

This case aside, there are cases of nephrotoxicity associated with aristolochic acids (AA) to which the MHRA has reacted accordingly, these products having generally been prescribed by practitioners under the UK’s ‘herbalist exemption’. Such products appear mostly to have been imported and sold illegally, or were manufactured in low-quality facilities within the UK, including Soho basements. Their toxicity tends to stem from the fact that the manufacturers have failed to follow traditional manufacturing practices that ensure that toxic fractions, such as AA, are largely removed in processing and manufacture. In other cases, the products were spiked with pharmaceuticals or contaminated, such products having always been illegal. The solution to these well-publicised issues is better policing and enforcement, not the herbal Directive!

It is unsurprising that the MHRA and other EU member state competent authorities decided to impose a general ban on use of *Aristolochia*. But concerns over excessive AA concentrations resulting from misuse of the herb, or incorrect, non-traditional

manufacturing methods, must not be used to damn every player within the sector that has not been able to gain registrations under the herbal Directive.

5. **Reclassification of Section 12(2) exempted medicines to botanical food supplements does not constitute a public health risk.** You indicate: *“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.”* **Clarification:** A product that may have been allowed to sell as a manufactured, unbranded, unregistered herbal medicine under the terms of Section 12(2) of the Medicines Act 1968 can, in some cases, be legitimately branded as a food supplement and sold, without posing any health risk to consumers. Should allegations of this nature be made, it is imperative that examples are given. The one example you cite is St John’s wort. In cases where food supplement versions have been sold, the dosage of hypericin is considerably lower than that used in medicinal variants of the same herb. In addition, precautions are typically given on the label.
  
6. **The European Court of Justice does not provide “an added complication”, but rather a solution.** You indicate: *“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.”* **Clarification:** The ECJ in a range of cases has not cast doubt, but rather tried to handle considerable legal uncertainty implicit in the extremely broad definition of a medicinal product (amending Directive 2004/27/EC, Article 1(2)) as it relates to herbal products. Accordingly, it has deemed that a medicinal determination can be made only when a product is weighed up in its totality, including the dosage of active ingredients (posology), their consequent likely pharmacological actions and the presentation of the product. This reasoning is also considered in the MHRA’s Guidance Note No 8, “A Guide to What is a Medicinal Product”. In the absence of this kind of clarification, the abounding legal uncertainty causes some to assume that all herbal products used for healthcare purposes should be deemed as medicines. You appear to be included among this number. Such a view is not compatible with the known effects of a great many commonly consumed food ingredients, many known for their beneficial and health restorative qualities that extend well beyond the mere provision of energy (caloric value).
  
7. **Does your complaint to the Secretary of State arise because you are concerned that companies that have secured THRs are disadvantaged by competition from food-supplement products which have not been, as expected, regulated out of existence?** You indicate: *“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.*” **Clarification:** As an independent academic, it is very surprising that you take this position. In fact, your position would seem to taint your scientific independence, and suggests that your primary concern is to protect one particular sector of the herbal industry with which you are likely to have close ties.

8. **Contrary to your view, the European Court of Justice has not questioned the legality of the Directive.** You state: *“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.”* **Clarification:** The ECJ has not questioned the legality of the Directive. As yet, there has been no judicial review of the Directive itself. The case law to which you allude considers individual herbal products in relation to their medicinal or food status. This is a quite separate issue to the Directive’s legality.

Owing to the fact that your misconceptions and inaccuracies may have seriously misled the Secretary of State for Health, I hope you will appreciate our reasons for putting this letter into the public domain. We have also sent a separate letter to the Secretary of State for Health about these issues, which is also now published on our website.

I would welcome a constructive response to the points I raise. Please address them to [info@anhinternational.org](mailto:info@anhinternational.org) and, to maintain the openness of the debate, I would also urge that you put them into the public domain.

Yours sincerely

A handwritten signature in black ink, appearing to read 'R. Verkerk', with a horizontal line underneath it.

Robert Verkerk PhD  
Executive and scientific director  
Alliance for Natural Health International

cc.

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