

From the Rt Hon Andy Burnham MP  
Secretary of State for Health



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The Rt Hon Tessa Jowell MP  
House of Commons  
Westminster  
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Dear Tessa,

- 2 DEC 2009

Thank you for your letter of 16 November raising the concerns of a number of your constituents about food supplements and herbal medicines.

On food supplements, the Government believes that regulation should be based on safety and consumers having the right to make an informed choice.

In the UK, food supplements are regulated under the *European Food Supplements Directive 2002/46/EC* which came into effect in mid-2002 and has applied since 2005. The Directive provides for the setting of maximum levels of vitamins and minerals in food supplements on the basis of science and safety.

Work on setting maximum levels is underway at European level and the Food Standards Agency (FSA) is representing the UK in this process. No specific maximum levels have yet been proposed. In the absence of levels, it is not possible to speculate on the potential effect of setting maximum levels on consumer choice. The timing for finalising any proposals is uncertain. However, the FSA will consult with stakeholders when the proposals are published.

Traditional herbal medicines fall under the remit of the Medicines and Healthcare products Regulatory Agency (MHRA). The Government's aim is that consumers who choose to use herbal medicines should have access to a range of products made to assured standards of safety, quality and patient information. It is important to remember that "natural" does not necessarily equate to "safe" and that medicines made from plants, just like any other medicines, can be potent, having a significant effect on the body. There is also an international trade in low grade unlicensed "herbal" remedies which are often found to be adulterated with heavy metals, undeclared pharmaceutical substances, or the wrong, toxic, herb. Examples of some of the safety issues regularly found are in Herbal Safety News on the MHRA's website at [www.mhra.gov.uk](http://www.mhra.gov.uk).

Until now, the market has been largely unregulated, with companies choosing what standards, if any, they will meet. UK consumers have been unable to identify which unlicensed herbal products are made to acceptable standards. This puts the public at

risk and responsible companies who follow high standards at a considerable commercial disadvantage.

The 2004 Directive on traditional herbal medicinal products requires manufacturers to meet the kind of standards for safety, quality and patient information that are accepted as the norm for other kinds of medicines. Manufacturers will need to have systems in place to ensure, for example, that the products contain the stated ingredients and are free from harmful heavy metals and other contaminants. Many companies across the UK and Europe with expertise in the safe manufacture of herbal medicines are clear that these standards are necessary. Research into consumer perceptions carried out by Ipsos MORI in 2008 for the MHRA showed that the public would like herbal medicines to meet assured standards.

The MHRA recognises that it is a major challenge for some herbal medicines companies to move into a regulated environment and so has implemented an extensive programme to help companies adjust. As at July 2009, 80 applications to register products under the traditional herbal registration scheme had been submitted, of which 37 had so far been granted (with the remainder under assessment) and more applications are expected to follow.

I hope this reply is helpful.

*Best wishes,*

A handwritten signature in black ink that reads "Andy". The signature is fluid and cursive, with a large initial 'A'.

**ANDY BURNHAM**