PRESS RELEASE

Unregistered black cohosh product associated with liver failure: this must not happen again

29th October 2012

An article in the Mail-on-Sunday yesterday reported that the Medicines and Healthcare Products Regulatory Agency (MHRA) has received a serious safety report linking the use of an unregistered black cohosh product of unknown quality with liver damage in a patient. The British Herbal Medicine Association says that this is a tragedy for the individual concerned and an important reminder of the need to regulate the supply of herbal medicines in the public interest.

Black cohosh (Actaea racemosa) is widely used by women to manage symptoms of the menopause. Since the full implementation in April 2011 of the Traditional Herbal Medicinal Products Directive (THMPD), all UK manufacturers of black cohosh and other herbal medicinal products have been required to register these with the MHRA. This registration involves the manufacturer assuring full medicine quality standards, detailed patient information leaflets and mandatory adverse effect monitoring. In the case of black cohosh medicines it has also been necessary for the products to carry a safety warning. So far nine black cohosh medicines have been registered under this legislation and the MHRA strongly recommends customers choose from this list.

However there are a number of non-registered products that have remained on the market in spite of attempts by the MHRA to restrict them. The particular problem with black cohosh is that adulteration with the wrong species is rife, with a number of published academic papers (see review paper below) citing a rate of around 30% in purchased samples. The adulterants are usually related species, often from China (black cohosh only grows in North America), and usually with uncertain safety profiles. Only the quality assurance of medicine production and the regulatory enforcement of these standards can prevent this adulteration.

The British Herbal Medicine Association has consistently called for strict controls of the supply of black cohosh since reports were published almost 10 years ago linking consumption of unregistered products to liver disease. Unfortunately, such black cohosh products remain a threat to public safety. It is important that robust steps are taken to enforce the Directive and ensure this tragedy does not happen again.

For further information contact the following BHMA representatives.

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Ends
In a review of the evidence of liver problems associated with black cohosh, *Health Canada*, in 2010, noted previous papers pointing to widespread adulteration in the market and concluded that their own cases “demonstrate that products not containing authentic black cohosh may be associated with liver adverse reactions”

[Canadian Adverse Reaction Newsletter Vol 20 • Issue 1 • Jan 2010](http://tinyurl.com/ydjmj5n)

The following are registered herbal medicines containing black cohosh that are available in the UK:

- Menoherb Tablets
- Boots Menolieve Black Cohosh Tablets
- Tesco Menopause Relief Black Cohosh Tablets
- Healthspan Menopause Relief Black Cohosh Tablets
- Higher Nature Menopause Relief Black Cohosh Tablets
- Menomood Menopause Mood Relief Tablets
- Kira Menopause Relief Tablets
- Menopret Tablets
- Rumatix Black Cohosh Oral Liquid

The British Herbal Medicine Association has since 1964 represented the interests of those who supply herbal medicines. Herbal medicines are quality assured, safe and effective solutions for the self care of many minor conditions that still impose unnecessary costs on the NHS.