

Press Release

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UK regulator warns of the importance of using registered herbal medicines after discovering super-strength menopause remedy

The Medicines and Healthcare products Regulatory Agency (MHRA) is urging consumers that natural does not always mean safe following a safety notice issued for FSC Black Cohosh 1000mg capsules, an unlicensed herbal remedy commonly used to relieve menopausal symptoms.

The MHRA has asked the manufacturer to remove the product from the market because it does not have the appropriate authorisation as a medicine and contains 50 times the approved dose for menopausal complaints. The product also had insufficient labelling detailing safety information and side-effects. It has been found online and is thought to be sold in independent health food shops.

Since 1998 the MHRA has received 50 suspected adverse reaction reports associated with various unlicensed black cohosh products. Whilst rare some of these reactions have included jaundice, liver problems and hepatitis.

There are black cohosh products with a traditional herbal registration (THR) available for the relief of menopausal symptoms which come with a patient information leaflet providing information about the correct use of the product as well as information on any potential side effects.

The MHRA recommends that registered herbal medicines are used. These can be identified by the THR registration number located on the packaging. The majority of products will also display the THR logo. These registered products will have been assessed and quality checked to ensure that they are acceptably safe to use.

Head of Herbal Policy Richard Woodfield emphasised this by stating, "This alert highlights the importance of using a registered product. If the product is not a THR there has been no guarantee relating to the safety or quality of the product.

"Reading the patient information leaflet ensures that you are aware of the correct way to take a medicine, the potential side effects as well as any possible interactions with other medication you may be taking.

Richard adds, “An unlicensed herbal product may have incomplete, inaccurate or no safety information and can mean you are gambling with your health, especially if you take these products without consulting a GP or qualified healthcare professional.”

Ends

Notes to Editor

1. Standards of safety and manufacture vary widely in the unlicensed herbal sector and the MHRA has issued a number of warnings about unlicensed herbal medicines and Traditional Chinese medicines. Under the UK traditional herbal registration scheme, introduced in 2005, manufactured over the counter traditional herbal medicines are required to meet standards of safety, quality and patient information. For further information, please see the hyperlink:

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON019609

2. The MHRA issued a safety warning about this product on 09 December 2011.

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Allherbalsafetyupdates/CON137756>

3. Herbal remedies should be used with the same caution and care as any other medicine as their use will have an effect on the body. While many herbal remedies are reasonably safe, it is important to remember that just because it contains natural ingredients and extracts this doesn't guarantee it is safe. People should always consult with a pharmacist or doctor to make sure that a herbal remedy is suitable for them to take and will not interact with any other medicines they may be taking.

Stay safe when using herbal remedies, follow us on Twitter @staysafeherbals

4. The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices, and take any necessary action to protect the public promptly if there is a problem. We encourage everyone – the public and healthcare professionals as well as the industry – to tell us about any problems with a medicine or medical device, so that we can investigate and take any necessary action. www.mhra.gov.uk