

Diapharm registers the first traditional herbal medicinal product containing St John's Wort and Black Cohosh

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Pharmaceutical service provider Diapharm has obtained the first traditional herbal registration for a fixed combination of St John's Wort and Black Cohosh in Europe. Both active ingredients are used to relieve the various symptoms of menopause, giving the combination a synergistic effect. One coated tablet of the medicinal product, registered by the British MHRA, contains 300 mg *Hypericum* extract and 6.4 mg *Cimicifuga* extract. "It is the first time that such a fixed combination of *Hypericum* and *Cimicifuga* has been registered in Europe as a traditional herbal medicinal product," says Dr Karim Sultan from Diapharm UK in London (www.diapharm.com).

The product is approved by the MHRA for the relief of symptoms of the menopause, including hot flushes, night sweats, slightly low mood and mild anxiety based on traditional use only. "We are now applying for further registrations in countries such as Austria, Hungary and France," explains Dr Karim Sultan. Diapharm never markets and distributes its products itself, but sells licenses of its registrations and dossiers to interested healthcare companies. As a pharmaceutical service provider, Diapharm focuses on regulatory aspects and then looks for partners, who have the capabilities to bring the products to market.

Sell-off period for unregistered herbal products

Approximately one quarter of all traditional herbal registrations in Europe originate with Diapharm. In the United Kingdom alone, Diapharm has prepared

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and documented 35 of the 79 newly registered traditional herbal medicinal products. "As the sell-off period in Europe expires on 30 April 2011, we expect another surge in demand for our dossiers and registrations", explains Dr Karim Sultan at Diapharm UK (www.diapharm.com). After this date, it will no longer be possible to sell unregistered herbal products. "For this reason, many manufacturers seek licences for dossiers and registrations in order to protect their product portfolios for the future."

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Photo caption (diamenocalm.jpg)

Diapharm expects an increasing demand for traditional herbal registrations like this newly registered combination of St John's Wort and Black Cohosh.

Background information: Diapharm

Diapharm is a full-service provider to the healthcare industry. Founded in 1988, Diapharm supports pharmaceutical companies in all questions concerning regulatory affairs, medical & clinical development, quality management and business development. Its activities focus on the sectors of medicinal products, food supplements and dietetic food, medical devices and cosmetics. With about 100 employees, Diapharm is at the service of multinational companies as well as of recent start-ups and small to mid-sized businesses.
