

Diapharm obtains six new THMP registrations

Austria and United Kingdom approve traditional herbal medicinal product for prostatic hyperplasia

London (UK), Vienna (AT), Münster (DE), 20. June 2011. Pharmaceutical service provider Diapharm (www.diapharm.de) has obtained a THMP registration for its *Urtica* film-coated tablets in the United Kingdom and in Austria. The authorities have approved the traditional herbal medicinal product (THMP) containing **dry extract of nettle root** for the “relief of symptoms of urinary tract discomfort in men who have been told that they have an enlarged prostate (benign prostatic hypertrophy or BPH), based on traditional use only. Prior to treatment other serious conditions should have been ruled out by a doctor.” The registrations in both countries can be acquired on licence by pharmaceutical companies.

“The indications for the *Urtica* product are a signal to the rest of the EU”, says Dr Rainer Kolkmann, welcoming the decision of the regulatory authorities. Dr Kolkmann led the development of the new products at Diapharm: “By including a reference to prior medical diagnosis, the Austrian authority AGES and the MHRA in the UK have found a practical way to guarantee the safety of patients.” Other regulatory authorities are often hesitant to approve prescription-free TMHPs for mild ailments if the symptoms to be treated could theoretically be caused by a serious underlying disease.

Diapharm has also registered its **Pelargonium root extract** in the UK and Austria “to relieve the symptoms of upper respiratory tract infections including common cold, such as sore throat, cough and blocked or runny nose”. In

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www.diapharm.com/pr.html*

Austria, the pharmaceutical service provider has also obtained approval for a traditional herbal combination product containing **Lemon balm, Valerian and Passion flower** with the indication “used for the temporary relief of symptoms of mild anxiety, to aid sleep and for mild digestive complaints, such as bloating and flatulence”. Furthermore, AGES has also approved a registration for **hawthorn, potassium aspartate and magnesium aspartate** “for use in the initial stages of reduced cardiac performance, with symptoms such as abnormal fatigue and tiredness on exertion”.

In total, approximately one quarter of the about 300 THMPs registered in Europe to date are based on Diapharm dossiers. The pharmaceutical service provider does not market any of the products itself. Diapharm concentrates on regulatory work and then out-licenses dossiers and registrations to partners who bring the medicinal products to market.

(approx. 2,430 characters)

Picture caption (DiaUrtica.jpg)

Diapharm has obtained six new THMP registrations, including dry extract of nettle root for the relief of the symptoms of prostatic hyperplasia.

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.
