

A first for Portugal: Diapharm obtains registration for a traditional medicinal product with Agnus Castus

Lisbon (PT), Münster, Oldenburg (DE), 25. June 2012 – Pharmaceutical service provider Diapharm (www.diapharm.com) has now also paved the way for traditional herbal medicinal products in Portugal. The Portuguese National Authority for Medicines and Health Products (INFARMED) has granted a second registration for a traditional medicinal product. “Historically, this type of registration is unusual for Portugal, and it is a sign that traditional herbal medicinal products for self-medication are gaining increasing recognition across Europe,” explains Dr. Rainer Kolkmann at Diapharm. The tablet containing Agnus Castus extract has been approved by the Portuguese authorities for the treatment of premenstrual symptoms. However, Diapharm will not be marketing the product itself. Instead, the company plans to license out the registration: “We are a service provider, not a manufacturer,” explains Dr. Rainer Kolkmann.

According to Dr. Rainer Kolkmann, herbal medicinal products often have regional traditions. One herb may have been established for decades in one EU country but can be almost unheard of in others. The THMP Directive 2004/24/EC is an opportunity to increase awareness of medicinal products such as these across Europe, but the industry and authorities have been hesitant at making use of the Directive. Pharmaceutical service provider Diapharm currently has around 20 dossiers and registrations for traditional herbal products in its portfolio and is ready to assign licensing rights and approvals to medicinal product manufacturers throughout Europe.

(approx. 1,570 characters)

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*Press releases from Diapharm and photo material in print quality may be downloaded from:
www.diapharm.com/pr.html*

Caption (Agnus_Castus_DIAPHARM.jpg)

Diapharm's tablets containing Agnus Castus extract have been approved for the treatment of premenstrual symptoms by the Portuguese authorities.

Background information: Diapharm

Diapharm is an international 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 in Germany, Austria, Romania and the United Kingdom, Diapharm is at the service of multinational companies as well as of recent start-ups and small to mid-sized businesses.
