

Diapharm achieves registration for combination product with Valerian, Passionflower and Melissa

For the first time, French regulatory authority ANSM approves a traditional, plant-based combination medicine: *Dormicalm*

Paris (FR), Monaco (MC), Münster, Oldenburg (DE), 09 November 2012 –

For the first time the French regulatory authority, Agence nationale de sécurité du médicament et des produits de santé (ANSM), has registered a traditional plant-based combination medicine. The product is presented as a coated tablet, with the three active substances Valerian, Passionflower and Melissa. ANSM granted the indication: for the relief of mild nervous tension and sleep disorders („*Médicament traditionnel à base de plantes utilisé pour soulager une tension nerveuse légère et les troubles du sommeil. Son usage est réservé à l'indication spécifiée sur la base exclusive de l'ancienneté de l'usage*“). The medication was developed by pharmaceutical provider Diapharm (www.diapharm.com), and is brought to market by FORTÉ PHARMA, Monaco, under the brand name Dormicalm.

FORTÉ PHARMA managed the application with the French authorities in accordance with the relevant regulations for implementing a Traditional Herbal Medicinal Product (THMP) in France. Dr. Rainer Kolkmann, responsible for product development at Diapharm, reported with appreciation, “This registration, eight years following the coming into force of the European THMP Directive 2004/24/EC, is a milestone for the medicinal market in Europe. It is a clear sign that traditional plant-based medication for self-medication has, in the meantime, received recognition across Europe. Countries that previously hesitated, such as France and Portugal are now proceeding along this path.”

Mid-year, the pharmaceuticals provider had, for the first time, achieved registration for a THMP in Portugal. Almost every fifth registration for

Contact:

Diapharm
Press Office
Hafenweg 18-20
D-48155 Münster

Contact person:
Nicole Sibbing

Tel.: +49 (0)251 - 60935-517
nicole.sibbing@diapharm.de
www.diapharm.de

Agency contact:

co-operate Wegener & Rieke GmbH
Zumsandstraße 32
D-48145 Münster

Contact person:
Christian Rieke

Tel.: +49 (0)251 - 3222611
wort@co-operate.net
www.co-operate.net

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

traditional plant-based medications in the EU can be directly attributed to the efforts of Diapharm. The main focus of the company, which has offices in Germany, the UK and Austria, is regulatory, medical and pharmaceutical advisory and support for marketing authorization applications.

(ca. 1,970 characters)

Caption (Dormicalm.jpg)

FORTÉ PHARMA, Monaco, received a registration by the French regulatory authority ANSM for a traditional herbal medicine containing Valerian, Passionflower and Melissa with the indication “for the relief of mild nervous tension and sleep disorders”. The coated tablets were developed by Diapharm.

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 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.