

## First "traditional registration" of an oral herbal medicine in the United Kingdom

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Category: [Health & Medicine](#)

Press release from: [DiapharmGruppe](#)

Agency: **co-operate Wegener & Rieke GmbH**

London, Oldenburg, 19 February 2007 – The traditional herbal medicinal product devil's claw (*Harpagophytum procumbens*) has been registered by Dr. Kolkmann & Partner GmbH ([www.diapharmgruppe.de](http://www.diapharmgruppe.de)) and MH Pharma UK Ltd. in Great Britain. It was for the first time that the British Medicines and Healthcare Products Regulatory Agency has registered an oral herbal medicinal product on the basis of its "traditional use". The holder of the registration is MH Pharma UK Ltd. The company will bring the medicinal product on to the British market from June 2007 under the brand name "FlexiHerb". The therapeutic indication will be the relief of backache, rheumatic or muscular pain, and general aches and pains in the muscles and joints, based on evidence of traditional use only.

"MH Pharma welcomes the close collaboration with Dr. Kolkmann & Partner GmbH which has culminated in the UK registration approval of our Devil's claw product." said Dr. Dick Middleton, Technical Director of MH Pharma UK Ltd. "We look forward to building on this successful platform in the future and creating a portfolio of registered high quality herbal medicinal products for the UK market in the coming years."

As stipulated by EU Directive 2004/24/EG, a large number of herbal medicines which are currently on the European market must be submitted to a registration procedure. In Germany this requirement covers especially the so-called "Section 109a marketing authorisations", whilst in Great Britain many herbal preparations which up to date have been marketed as unlicensed herbal medicines must also be submitted for registration. The prerequisites for a registration as a traditional herbal medicinal product are – among others – the proof of pharmaceutical quality as well as the evidence that the product has been continuously used during the past 30 years, the so-called "evidence of tradition".

(approx. 1,880 characters)

Background information: DiapharmGruppe

The DiapharmGruppe offers comprehensive and individual regulatory services and pharmaceutical consulting to companies in the health product sector, for an optimal management of the portfolio of medicinal products and health products. Upon individual request the DiapharmGruppe consisting of a team of about 60 qualified staff members performs the strategic planning, management and responsible maintenance of complete product portfolios. The business volume of the group amounts to 10 Mio Euro. The DiapharmGruppe consists of the following corporations: the Dr. Stefan Sandner GmbH (Pharmaceutical Management & Portfolio Solutions), the Dr. Kolkmann & Partner GmbH (Drug Registration & New Projects), the Dr. Middeler et al. GmbH (Biotechnology & Medical Devices), the Zentralinstitut Arzneimittelforschung GmbH (Analytics), the Dr. Ebeling & Assoc. GmbH (Medical Affairs & Pharmacovigilance), Beate Beime & Team (Clinical Research Coordination) as well as the HÄLSA Pharma GmbH (Responsible Manufacturer & Product Release).

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