

China and Europe foster the internationalisation of TCM

Chengdu (CN), Münster (DE), 27. October 2016 – “Europeans think highly of Traditional Chinese Medicine, but so far only a few TCM products have made their way into the EU”, observed Diapharm’s Dr Rainer Kolkmann at the 5th International Conference on the Modernization of Traditional Chinese Medicine (TCM) in Chengdu, China. But Kolkmann also said that the European Medicines Agency and its Committee on Herbal Medicinal Products, HMPC, are “open-minded” to TCM products coming to Europe: “The harmonisation of assessment practices for herbal substances of non-European origin is explicitly included in their work programme.” In his speech, the Head of Product Development at one of Europe’s leading regulatory service providers (www.diapharm.com) explained how to successfully register TCMs in the European Union. Dr Rainer Kolkmann had been invited as a foreign vice president to the conference’s TCM innovation panel. The conference with 1,500 participants took place on 24-25 October in Chengdu, the capital of Sichuan Province, China.

The main reasons why – despite high demand – only few TCMs are actually available in Europe, are the different regulatory frameworks in China and the EU, Dr Kolkmann said. During his speech he outlined the various registration strategies for TCMs in Europe. Traditional herbal registrations, for example, are considered to be relatively fast and straightforward, but they are only available for herbal ingredients with a long tradition of use. Diao Xin Xue Kang capsules and joint and muscle relief tablets based on Xiangxue, for example, were successfully registered in the Netherlands and in the UK respectively, because their ingredients have been used for at least 15 years in Europe. The active ingredients of Sanchi-tongshu capsules, on the other hand, are yet unknown in Europe. Huasun Group, the Chinese manufacturer of the product,

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therefore opted for a full application, which will include submitting pre-clinical and clinical trials to the European authorities, with Diapharm as its local service provider in Europe. Diapharm has partnered with the China Chamber of Commerce for Import & Export of Medicines & Health (CCCMHPIE) and its more than 2,400 member companies in order to bring Chinese medicines to Europe.

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Photo caption (Kolkmann_Rainer_DIAPHARM.jpg)

Europeans think highly of Traditional Chinese Medicine, says Dr Rainer Kolkmann, Head of Product Development.

Background information: Diapharm GmbH & Co. KG

Diapharm (www.diapharm.com) is a leading global consulting firm and service provider for the consumer healthcare and pharmaceutical industry. Founded in 1988, Diapharm supports clients in the fields of medicinal products, medical devices, food supplements, dietetic foods and cosmetics. Its work focuses on regulatory affairs and marketing authorisation, medical and scientific tasks, quality assurance and consulting. With around 100 employees in Germany, the United Kingdom, Austria and China, Diapharm supports multinational corporations, recent start-ups and medium-sized companies.
