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# Drug manufacturers discuss herbal products

London (UK), 18 April 2011. "Patients must have confidence that herbal medicinal products are safe." These are the words used by Dr Karim Sultan, Head of Diapharm UK (www.diapharm.com), to summarise discussions at the THR holder meeting in London on Tuesday (12 April 2011). The gathering brought together approximately 20 participants, comprising manufacturers and registration holders of traditional herbal medicinal products (THRs). The group agreed to join forces in an association whose functions would include campaigning for the safety of herbal medicinal products.

Dr Rainer Kolkmann, also of Diapharm, joined Dr Karim Sultan to advocate such an association. Diapharm is one of Europe's leading service providers for traditional herbal medicinal products. More than 40 percent of registrations in the United Kingdom and approximately 25 percent of all traditional herbal medicinal products in Europe are based on Diapharm's dossiers.

### Transition period for "unlicensed herbals" ends on 30 April 2011

The seven-year transition period for formerly unlicensed herbal products ends on 30 April 2011. From that time onwards, medically active products such as St. John's Wort, Echinacea and Valerian will have to be registered as medicinal products. Consequently, pharmaceutical quality standards as GMP will apply to their manufacture. "Customers will see a triple benefit thanks to these more stringent requirements. As the extracts and compositions have to be tested, customers can depend not only on the safety of a product, but also benefit from higher quality and efficacy," argues Dr Karim Sultan. After the end

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of the transition period on 30 April, it will still be possible to run down existing stocks of old, unlicensed products at pharmacists and retailers. However, experts expect that there will subsequently be violations. Participants at the THR holder meeting discussed this with Richard Woodfield, Dr Linda Anderson and David Carter of the Medicines and Healthcare Products Regulatory Agency (MHRA): "The MHRA must be thorough in the implementation and enforcement of the new regulations, and it must protect the safety of the patients," says Dr Karim Sultan.

(approx. 2,200 characters)

## **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.