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## A Practical Guide to Licensing Herbal Medicinal Products

**Do you manufacture herbal products?**

**Have you applied for registration of your products yet?**

Licensing of herbal products in the UK and European Union is changing. The Traditional Herbal Medicinal Product Directive (THMPD) was implemented in the UK in 2005 and allows herbal products to be registered under medicines law. By 2011, every pharmaceutical company manufacturing herbal medicines that are sold in the UK and European Union must have obtained a market authorisation.

**As a manufacturer of such products, you need to ask the following:**

- What type of herbal products are you manufacturing?
- Are you required to license your herbal products and what type of license do you need?
- Would your product comply with regulations?
- What evidence and manufacturing data do you need to provide?
- What are the packaging and leaflet requirements for your product?

**And most importantly:**

- How do you apply for a license?

*A Practical Guide to Licensing Herbal Medicinal Products* is a handbook soon to be published by Pharmaceutical Press that answers all these questions and also provides full guidance on license application, including how forms should be filled in, who they should be submitted to and what costs are involved. As part of the publication process, the text was subjected to rigorous review by eminent experts in the field, including the Medicines and Healthcare products Regulatory Agency (MHRA).

All the official legal guidelines and forms are included within the book, which also includes step-by-step guidance on filling out the application forms.

Published in ring-binder format – this book will be easy and practical to use in guiding you and your company from the initial decision making process through to receiving a license.



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**Written by experts in the field, authors include:**

**Thomas Brendler**, Director of Plantaphile, is a consultant and ethnobotanist with a number of phytomedicine books and publications to his credit. As well as developing and managing projects for industry on the use of plants in medicine, food and cosmetics, he is involved in medicinal plant research around the world, focusing on Africa and the Pacific Islands.

**L Denzil Phillips** is Founder Director of Denzil Phillips International, a company specialising in commercial research and development in the field of medicinal and aromatic plants and related botanical substances. Denzil has worked on developing herbal products with international corporations, private exporters, banks, governments and international development agencies in more than 30 countries.

**Stefan Spiess** is Managing Director of Gruenwalder Gesundheitsprodukte GmbH. Stefan is a qualified pharmacist and food chemist. As head of regulatory control for the Hexal group, he supervised over 300 product license applications. He is a QP and a specialist on pharmaceutical expert reports, stability testing and registration strategies.

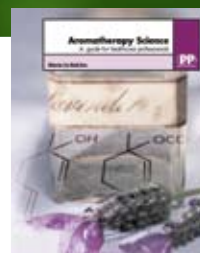
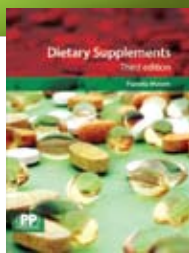
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