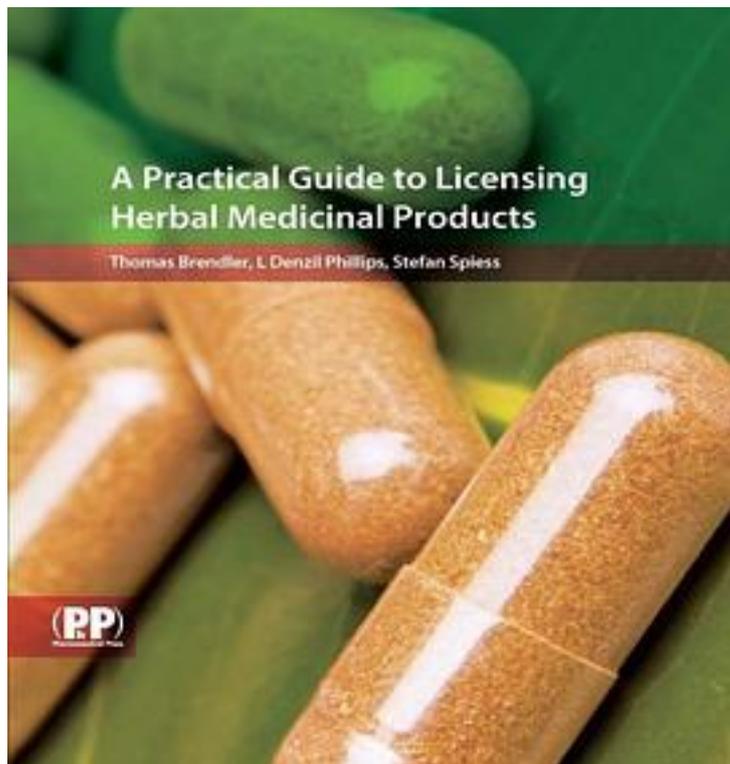


A Practical Guide to Licensing Herbal Medicinal Products



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This is a practical guide to aid pharmaceutical companies with registration of herbal products. The THMPD allows herbal products to be registered under medicines law. To gain this registration, these products must demonstrate high (pharmaceutical) standards of manufacture and product quality. Other options for manufacturers are to gain a marketing authorization category for a product called "well-established use" or to register their product under the category of a herbal food supplement. The law

therefore establishes a means for companies to decide within which category to market their products. The decision depends, to some extent, on the amount of data available or the level of claim they wish to make. This guide is intended to be used as a manual/workbook to give practice help and instructions on accomplishing these tasks. The guide includes all available information and documents in the entire registration procedure from initial decision making through to receiving a license or rejection.

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