

# Herbal Products



***The recently introduced European simplified registration procedure for herbal medicinal products allows the registration of such products without requiring detailed information from trials of safety and efficacy, provided that there is sufficient evidence on the medicinal use of the product throughout a period of at least 30 years, including at least 15 years in the Community (Article 16a to 16i of Directive 2001/83/EC, Directive 2004/24/EC). Applications are required in CTD format and can be made on the basis of bibliographic or expert evidence supporting the efficacy and safety of the medicinal product, complemented by any additional data, which the Member State's competent authority may request. The manufacturing and quality data requirements for herbal medicinal products under this scheme are equivalent to applications for a marketing authorization. In addition labelling, SPC and PIL information as well as CV's from experts who have supported the safety and traditional use of the product are required.***

## ***Inspired solutions in a regulated world.....***

- Unicus has over 10 years of success in preparing high quality CTD submissions for all types of medicinal products.
- Dedicated and experienced experts in the field of herbal medicinal products can assist you in the interpretation of what the requirements are for your product both in the UK and the rest of the EU.
- Successful track record in liaising with the MHRA's Borderline Unit to establish the likely classification for a number of products and agreement on the future requirements to market these products in the UK.

**Unicus can help you navigate through the legislation and regulatory requirements to ensure your product complies with all necessary requirements and reaches or continues in the market place with minimal delays.**



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