SERVICE SHEET

WAINWRIGHT associates
Regulatory Affairs

EU Registration

We can determine whether the Centralised, Decentralised or Mutual Recognition Procedure best fits your objectives.

A guide to Europe

Our experienced team is qualified to advise on all the scientific disciplines required for successful Marketing Authorisation Applications in Europe. Where there is flexibility, we can determine whether the Centralised, Decentralised or Mutual Recognition Procedure fits best with the client's objectives. We make sure that the full range of presubmission support is taken into account, so that the most can be made of Small and Medium-sized Enterprise (SME) status, regulatory and scientific advice, as well as paediatric and orphan incentives, according to the individual circumstances.

When it comes to submission and handling the procedure, your application is in safe hands. We know how to present and justify data in the way that maximises success. High quality, professionally published submissions are now expected by all regulatory authorities and use of the eCTD is increasingly demanded. We ensure that the published output bears the high quality and user-friendly finish that creates the right impression and facilitates review through validation, assessment and approval.

Pre-submission planning

In Europe, the regulatory system is designed to assist all kinds of company and product, and bringing Wainwright Associates on to your team at an early stage can bring rewards. There are attractive incentives for SMEs and companies developing medicines for orphan indications. We can advise you on likelihood of qualification as well as submit on your behalf to gain the desired status and access to the incentives.

For new medicines, a Paediatric Investigational Plan (PIP) or waiver needs to be submitted early on. The need to consider all groups in the paediatric population means this can be an intense undertaking at a busy time, when there also remains a lot to be learnt in the adult population. However, the rewards can be substantial, with an additional 6 months of patent protection. For established active substances, a potential 10 years of data exclusivity in the paediatric indication is designed to entice generic companies to consider paediatric development.

Scientific advice is encouraged and with the availability of both national and centralised advice, the best tactical route at a given stage of development needs to be decided. With its procedural expertise, ability to identify and crystallise the scientific issues and

WAINWRIGHT associates

EU legislation need not be daunting. With the right support, it can provide real competitive advantage.

considerable experience in preparation of the supporting documentation and presentation of the questions and company position, we make sure that you get the most out of scientific advice.

The EU legislation need not be daunting and with the right support can provide competitive advantage. Our team can guide you on the regulatory strategy.

Marketing Authorisation Applications

After all the hard work of the presubmission phase, you want to see the results from your investment in a successful application. With our extensive experience in Centralised, Mutual Recognition and Decentralised Procedures, your application is in safe hands. We can handle the whole or part of the process and depending on the procedure, activities can include:

- Organisation of presubmission meeting with Rapporteur/Reference Member State and EU/national scientific advice
- Preparing or updating the dossier, including the quality overall summary and non-clinical and clinical overviews
- Preparation of the EU Module 1 including product literature, readability testing and description of the pharmacovigilance system
- Invented name application
- Obtaining Assessment Report from Rapporteur/RMS
- Arranging translations and preparing documentation for all countries
- Payment of fees
- Publishing in eCTD*
- Dossier despatch
- Assuring validation and clock start
- Reviewing questions from the authorities and preparation of responses
- Co-ordination and submission of responses and liaison with the authorities

*We publish and manage submissions across the full spectrum from paper, non-eCTD electronic submissions, to eCTD and ensure that your submission is compliant with the individual requirements of the receiving regulatory authorities.

Contact us:

For a more detailed discussion on how we can help you, contact us on **+44 (0)1628 530554** or email us on **info@wainwrightassociates.co.uk**

www.wainwrightassociates.co.uk