

A SUMMARY OF REGULATORY EXPERIENCE

WMJ Consulting Limited

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A Summary of Regulatory Expertise

We have provided an integrated range of regulatory services from regulatory strategic consulting, IND and CTA submissions right through to compilation and submission of regulatory dossiers using Electronic Common Technical Document (eCTD).

We have in-depth knowledge and practical experience of the process and procedures used in both the US and European Union (EU), with first hand experience of successful submissions to the FDA and the European Union Competent Authorities (CA) as well as considerable experience with regulatory authorities from outside of these geographical regions including Switzerland, Central and Eastern European Countries (CEEC), Asia and Australasia.

The breadth of our experience includes a full understanding of the impact of the EU Clinical Trial Directive (2001/20/EC) relating to the execution and management of clinical trials across Europe.

The range of regulatory activities we have been engaged in has included the following:

- Strategic consulting and regulatory document writing, meeting arrangement and participation for an EOPII meeting at the FDA (US) for anti-dementia product.
- The preparation, submission and management of all activities required for obtaining approval for 3 centralized oncology marketing authorizations in the EU. This included writing and compilation of the Chemistry/Pharmacy, Pre-Clinical and Clinical documentation.
- Development of the regulatory strategy and involvement in the preparation and submission of a Marketing Authorisation Application (MAA) to obtain the successful approval via the EU Centralized Application process for a product to treat Gaucher's disease
- The complete preparation and submission of them MAA for an oncology product via the EU Mutual Recognition process. Approval was obtained in nine European Member States (MS).
- The successful preparation and submission of 2 European Orphan Medicinal Product Applications within the Anti-virals therapeutic area.
- The successful preparation and submission of 3 European Orphan Medicinal Product Applications within the Oncology therapeutic area.
- Regulatory input into on-going clinical development programmes for products developed for the treatment of:
 - Chronic Angina
 - Diabetes
 - Cervical cancer
 - Hepatocellular cancer
 - Renal cancer
 - Psoriasis
 - Gastroenterology

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- Sexual dysfunction
 - Congestive Heart Disease – using cell based therapy
 - Hereditary angiodema
 - Parkinson's Disease
 - Bi-polar Disorder
 - Depression
 - Amyloidosis
- The co-ordination and submission of four national applications in Sweden, Denmark, France, Switzerland and United Kingdom (UK) for hormone replacement therapies.
 - The preparation of the application and full co-ordination of 7 requests for Scientific Advice to the CPMP (now CHMP – Committee for Medicinal Products in Human Use) of the European Medicines Agency (EMA) in multiple therapeutic areas. Three were concerning oncology products, two were for cardiovascular treatments and the final two were in Emerging Therapies.
 - Coordination of the preparation and lead participation in a number of requests for Scientific Advice from the national CA of the EU and in general the successful achievement of a consensus with the national CA for the concerned MS of the submitted clinical development plans.
 - Extensive experience in preparing, submitting and obtaining approval for clinical trial notifications throughout the EU, Central and Eastern Europe, Russia, South Africa, Australia and New Zealand.
 - Practical and varied experience in seeking and obtaining permission to conduct clinical studies with Investigational New Drug's (INDs) in the US.
 - Broad experience with the Medical Device Directive (93/42/EC) and with the requirements for conducting clinical trials in the EU with medical device(s), which have not being CE marked.
 - Regulatory Project Leader for a submitted CTD based Application for a Marketing Authorisation (AMA) of an Orphan Medicinal Product (cardiovascular) in the US and the EU using a Document Management System (DMS) to prepare the final eCTD. Approval in the EU via the CP has now been given (May 2008).
 - Regional regulatory management of Gastrointestinal and Allergy therapeutic franchises for the European region (covering EU, CEE, South Africa, Israel, Australia and New Zealand).
 - Acting as Regional Representative on global project teams for products undergoing SmPC harmonisation within the EU (article 30 procedures). Provision of advice to local subsidiaries of EU regulatory requirements and procedures. Determination of EU regulatory strategy and ensuring this is consistent with overall global strategy.
 - Clarification of post harmonisation procedural issues with the Mutual Recognition Facilitation Group.
 - Coordination of post – harmonisation activities including national implementation of harmonised SmPC, post approval commitments, subsequent chemistry/pharmacy harmonisation implementation.
 - Coordinating regulatory submissions with national operating companies of

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global pharmaceutical company for both Mutual Recognition and nationally authorised products. These submissions included renewal applications and variation applications.

- Support to local operating companies and licences of a global pharmaceutical company in responding to direct requests from their National Authorities for SmPC updates / renewals and other maintenance activities. Including initiation of Global Core Data Sheet reviews and coordination of the relevant responsible departments (such as Drug Safety, medical or preclinical) within the Global Corporation.