CASE STUDY

SPECIFIC SERVICES FOR EUROPE

Define & implement the European Health Authorities consultation strategy for a US-based client

BlueReg made recommendations to a US based client on which Health Authorities in the European Union (EU) would be most relevant to consult throughout the development of their product. Following these recommendations, the client subsequently entrusted to BlueReg the authoring of a Briefing Package and the management of the regulatory procedure for a national Scientific Advice consultation on its behalf.

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Challenges

This project consisted in providing regulatory and scientific writing support in the development of a promising monoclonal antibody, being investigated in a Phase 2b clinical study with the following constraints:

- Several meetings and extensive communications had previously occurred with the Food and Drug Administration (FDA), all resulting in a US-oriented development program for this product.

- The targeted indication was complex and covered multiple therapeutic areas.

BlueReg support

BlueReg put in place a team of highly experienced consultants with solid expertise in global drug development and registration to meet the client and project's needs.

A project manager and Regulatory expert:

- Acted as the main contact person for an optimal coordination of all activities.

- Agreed clear timelines and organised regular meetings with the client to ensure efficient interactions.

- Provided regulatory executive input to the proposed European Health Authorities (HAs) consultation strategy.

A Regulatory Affairs and Scientific Writing expert:

• Regulatory actions:

- Performed a detailed review of HAs' expertise in the European Union (EU) in the targeted indication and for the product's key competitors.

- Recommended an EU HAs' road map for scientific advice throughout development.

- Reviewed the FDA briefing package against EU requirements and adapted the EU HAs consultation's strategy accordingly.

- Managed the National HA Scientific Advice regulatory procedure.

• Scientific writing actions:

- Proposed a timeframe throughout development for briefing books preparation to support the recommended EU HAs consultations.

- Authored the European Scientific Advice briefing book:

• Updated the background information on quality, non-clinical and clinical aspects of the product and its development.

• Wrote questions and company positions tailored to EU requirements and the agreed strategy.

Achievements

- BlueReg recommended a well-defined EU HAs' road map specific to the client, its product and the targeted indications; the provided guidance was fully endorsed by the client, allowing timely EU HAs consultations throughout development.
- BlueReg produced a high-quality European briefing Book, fully compliant with EU requirements and EU HAs' expectations.
- The client recognised the high regulatory and scientific expertise of the BlueReg consultants and was thankful for the team's contribution to the invaluable European scientific advice received for their product.

How BlueReg can support you ?

Specific Services for Europe

BlueReg has a dedicated team of experts who cover the whole development process from concept to approval, on centralised and multi-national projects. Our consultants have diverse experience ranging from regulatory strategy to operational execution and full project management support will be provided.

• Services provided by our team include:

- Development strategy and advice
- Interactions with regulatory agencies
- Clinical Trial Applications (CTAs)
- Scientific Advice (European Medicines Agency and national agencies)
- Orphan Drug Designations (ODDs)
- Paediatric Investigation Plans (PIPs)
- Drug registration and registration strategy
- Marketing Authorisation Application (MAA) dossier preparation
- Post MAA regulatory maintenance
- Regulatory publishing
- Regulatory support
- Local in-country support services and regulatory support

Coordination and regulatory support across Europe

This service can be utilised during the entire registration process, through to launch and post marketing activities. BlueReg can guide you through the country to country requirements for local regulatory strategy, launch preparation, promotional copy review, healthcare compliance, pharmacovigilance, quality, supply chain, labelling review, pricing and reimbursement and post approval submissions. We provide local in-country resources and support as required.

Support is provided through our in-house team utilising, when required, the support of our qualified worldwide partner network who have significant national experience. BlueReg will provide full project management for all engagements from single market to multi-country / multi-regional projects with assignment of a designated project lead. Our services can supplement client in-country resources or we can undertake all market activities on your behalf as required.

We will provide a flexible approach designed to fully support your needs which will be adapted as the project evolves. All activities are carried out in compliance with local and regional regulatory requirements.

For more information please contact us

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