Support for CHMP Scientific Advice

Two global companies recently entrusted to BlueReg the management of a Committee for Medicinal Products for Human Use (CHMP) Scientific Advice procedure. Scientific Advice procedures not only give the Applicant the perfect opportunity to build an early, good, and trustworthy relationship with the Regulatory Authorities, but also greatly increases the chances of successfully bringing a product to market when the received advice is taken into consideration in the development program.

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Challenges

- The projects involved scientific writing and regulatory support from BlueReg, for generating the briefing document, compiling/preparing the Scientific Advice briefing package and submission to the European Medicines Agency (EMA), with tight submission dates for the start of the CHMP Scientific Advice procedures.

- The Scientific Advice procedures were key to both clients as their respective products were the first potential Market Authorisation Application (MAA) submissions in Europe. During these projects, a strong relationship was built, with the clients putting their full trust in BlueReg's expertise in European Scientific Advice submissions.

BlueReg support

Throughout the years, BlueReg has gained extensive experience in not only CHMP Scientific Advice, but also in Scientific Advice with many national competent authorities. BlueReg put together a dedicated team of experienced consultants with appropriate regulatory and scientific writing expertise, and project management skills to meet the regulatory submission requirements and to best satisfy the clients' high expectations.

Collectively, the BlueReg team prepared a risk and mitigation assessment for the Scientific Advice procedure, which was discussed with the client, in order to ensure that the Applicant's positions reported in the briefing document was as robust and complete as possible and also to anticipate any potential issues that the Scientific Advice Working Party (SAWP) may wish to raise and subsequently address at a possible discussion meeting.

A project manager

- Acted as the main BlueReg contact with the client;

- Ensured the project team was fully supported and all timelines were met.

Regulatory team of consultants, experts in Scientific Advice:

- Provided advice/guidance to the clients on all expected steps and interactions with the EMA;

- Worked closely with the scientific writing team to ensure that regulatory guidelines were strictly followed, or that a full justification/rationale was otherwise given;

- Presented key timelines and milestones to the client, ensuring the briefing document was authored, reviewed and submitted on time;

- Ensured that the submission was made and validated on time and that the procedure ran smoothly throughout;

- Highlighted that the core product team and Key Opinion Leader's availability was imperative during the period of the procedure where a List of Issues and a discussion meeting were a possibility;

- Ensured all EMA correspondence was shared with the client immediately upon receipt.

Scientific writing team of consultants, with experts in Chemistry, Manufacturing and Controls (CMC), non-clinical and clinical

- Provided advice/guidance to the clients on the questions to ask the EMA;

- Authored and/or reviewed the CMC, non-clinical and clinical areas of the briefing document;

- Worked closely with the clients' CMC, non-clinical and clinical experts to strengthen the briefing document, in particular following BlueReg's risk and mitigation assessment;

- Provided overall strategic input and positioning.

Achievements

- Preparation and submission of draft Letter of Intent (LoI) and draft briefing package in accordance with EMA timelines;
- Pre-submission meeting with EMA, update of the draft LoI and briefing package as per EMA recommendations;
- Submission and successful validation of the final LoI and briefing package in accordance with EMA timelines;
- BlueReg efficiently liaised with EMA and managed all timelines to ensure a smooth and timely procedure;
- BlueReg was successful in conveying the complexities of European submissions and timelines to global clients;
- Development of strong path to MAA submission following Scientific Advice;
- BlueReg accomplished full client satisfaction, with great appreciation of the team's expertise and built a strong relationship for future European submissions.