Challenging European policy proposals with an evidence-driven submission on behalf of a cross-industry consortium

What our client needed

We were approached by a consortium of global pharmaceutical and medical device companies who were concerned about proposed new European legislation that would impact the group's products and detrimentally impact patient care.

The proposed legislation aimed to restrict the manufacture and use of a substance, due to potential risks to the environment and human health. The substance is used in a wide range of industries and is a necessary component of some medical devices and pharmaceutical products.

Collaborating above brand, these companies sought a partner to develop an evidence submission that outlined their concerns and made the case for the continued use of their products. They were anxious to convey the essential nature of the products for maintaining standards of care, and present a sector-wide consensus on the issue.

With a short deadline (7 weeks from project initiation to final submission) and multiple stakeholder organisations, the project needed expert management.

How we supported them

We conducted a targeted literature review of the treatment guidelines specified by professional medical societies in France, Germany, Italy, the Netherlands, and Spain. We used this information to map an overview of the current standard of care in all five markets, highlighting where the products in question feature as an essential part of treatment.

A second targeted literature review identified the current research and development pipeline for potential alternative products. This highlighted that there are currently no alternatives, and a low likelihood of alternatives becoming widely available within the next 15 years.

Using these insights, we surveyed 16 subject matter experts, with an average of 25 years' clinical experience in this disease area, about the utility and importance of the consortium's products.

The outcome

We submitted an impactful report that combined insights from the targeted literature review and expert opinions from the survey. The submission included a prospective risk-impact assessment to quantify the impact of the proposed ban on patient outcomes, as well as direct and indirect costs to society and the healthcare system.

The report gave a comprehensive overview of the baseline scenario, the necessity of the products in question, and the detrimental impact of the ban.

In addition, C-level executives and presidents at each of the sponsoring companies provided their signatures on the final report. This gave significant weight to the evidence submission and supported a compelling argument for why these products should be exempt from the proposed ban.

How we added value

Expert project management enabled us to manage each client company and support their timely input and review into each of the project components, within the 7-week timeframe. As an external partner, we were able to submit the final response as an impartial party, which the sponsoring companies would not have been able to do without our contribution.