

Case Study

Supporting a biopharmaceutical company not established in Europe accessing SME incentives granted by the European Medicines Agency



A US based client entrusted the European legal representation and the application/granting of their SME status to BlueReg. BlueReg coordinated the client's SME dossier preparation and submission to EMA, optimising the application content to expedite its approval.

Challenges :

This project consisted in supporting a medium sized enterprise not established in the European economic area (EEA) to access the micro, small and medium sized enterprise (SME) incentives granted by the European Medicines Agency (EMA), through the BlueReg SME status, in accordance with the Commission Regulation (EC) 2049/2005 and EMA user guide for SMEs.

Constraints were related to very tight timelines in the preparation of the client's SME application, the overall review of the legal and financial information, and the finalisation of the full dossier for a timely submission to the SME office at the EMA.



BlueReg support:

BlueReg put in place a dedicated team with extensive knowledge in legal SME purposes/incentives and a solid regulatory expertise in SME status application.

A project manager:

- Acted as main contact point with the client.
- Ensured coordination of activities between the client and BlueReg consultants, and organised follow-up meetings.
- Provided advice to the client on the administrative and financial SME incentives.

A Regulatory Affairs Expert:

- Provided operational support in collecting the required documentation from the relevant stakeholders to put the client's SME dossier together.
- Reviewed the legal and financial information provided by the US based company to identify and anticipate potential EMA questions.
- Submitted and closely followed-up with the EMA/ SME office on the client's dossier up to its approval.
- Was in charge of the maintenance of both (BlueReg and US based client) SME status, including acquisition/merger and renewal.
- Acted as main contact point for the EMA/SME office on the client's behalf.



Achievements:

- The client's SME status application was prepared, submitted on behalf of the US based company and granted within the short timelines agreed.
- The client was thankful for BlueReg support and guidance throughout the application process and acknowledged BlueReg regulatory expertise on SME status within EU.
- The client's SME status enabled the US based company to benefit from administration and financial incentives as defined in the Commission Regulation (EC) 2049/2005, through BR acting as their EU legal representative.

