CASE STUDY

SME REPRESENTATION

Supporting micro, small and medium sized enterprises (SMEs) not established in the European Economic Area (EEA) in accessing incentives granted by the European Medicines Agency (EMA)

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.

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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 consultant:

- 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'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.
- The client was thankful for BlueReg support and guidance throughout the application process and acknowledged BlueReg regulatory expertise on SME status within EU.

How BlueReg can support you ?

SME Representation

BlueReg is registered as SME (Small and Medium-sized Enterprises) by the EMA and can support non European economic area (EEA) enterprise by accessing micro, small and medium sized enterprises (SMEs) incentives granted by the EMA through the BlueReg (BR) SME status, per the Commission Regulation (EC) 2049/2005 and EMA user guide for SMEs.

The SME criteria are based on the enterprise's size e.g. number of employees, annual turnover and ownership structure. If SME companies are not established in the European Union (EU)/European Economic Area (EEA), SME incentives can be accessed through BlueReg regulatory consultancy who has the SME status.

BlueReg and their EMA approved SME clients have access to several benefits such as administrative, regulatory and financial support (e.g. EMA fee reductions for scientific advice, inspections and post authorisation procedures; EMA fee deferral until outcome for a marketing authorisation application).

BlueReg coordinates SME client status dossier preparation and submission. BlueReg can also optimise the application content to expedite the approval by EMA. In terms of methodology, BlueReg will assign a project manager who will act as main contact point with the client and coordinates BlueReg consultants and related activities.

The regulatory consultant(s) will provide the operational support by collecting the required documentation from the relevant stakeholders to put the client's SME dossier together. Submission and maintenance of the SME dossier is under his/her responsibility. The consultant will act as main contact point for the EMA/SME office on the client's behalf.

Why work with BlueReg ?

The values of BlueReg, Integrity, Team Spirit, Commitment, and Agility, are engendered by the staff we employ. The fact that many originate from similar pharma companies as our clients means there is an inherent understanding of the pressures and constraints that are faced and working relationships are collaborative and rather 'un-consultancy' like.

For more information please contact us

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