Case Study

Preparation, submission and coordination of a Centralized Procedure (CP) for PUMA formulation

Challenge

Needed expertise for regulatory strategy and support for execution for CP and PUMA formulation

- A small European pharmaceutical company has identified the need for support due to lack of capacity and capability to process a centralized procedure for a PUMA formulation.
- PharmaLex offered support for various regulatory activities in relation to the preparation, submission and coordination of the centralized procedure.
- Project management.
- Definition and tracking of KPIs and budget.

Solution

Defined development strategy and support execution of recommendations

- Support of regulatory relevant initiatives and business projects of the client, including EMA interactions of all regulatory activities for PUMA formulation.
- Coordination with EMA (e.g. letter of eligibility, name review application, pre-submission meeting).
- Preparation, compilation and submission of the corresponding complete dossier format to EMA and obtaining Commission Decision (CD) within the timelines.
- Coordination and support during validation, response phase and post CP phase until CD.

Outcome

PUMA approval

- Commission decision obtained 14 months after start of the procedure.
- The successful marketing authorization for the fourth human medicinal product PUMA in the EU was granted.
- Performance measurement via KPIs.