

BUSINESS CASE

Case Study: Marketing Authorization Expansion in Europe

CHALLENGE

Client without prior European regulatory knowledge and with the objective to expand its business internationally

A small European Pharmaceutical company with local activity in its country, with a growth strategy aiming to expand to international markets but lacking experience and capability in managing complex EU procedures.

SOLUTION

Outsourcing of global registration strategy and role of applicant (MAH) during procedure and up to approval

Asphalion prepared a **5-year plan** to register **7 products** in **20 different European countries**.

This was carried out by submitting the following procedures:

7 DCPs **4** RUPs **5** NP

Activities performed:

- **Strategic reports** to determine the best strategy for registration.
- **Gap analysis** according to the latest EU requirements.
- Coordination with the different **Health Agencies**.
- Preparation, **compilation, submission** and publishing of the complete dossier.
- **Follow-up** of applications: Coordination and support during **validation** and **response phase**, until authorization granted.
- Performance of **dossier maintenance** activities (MA transfers, variations, PSURs,...).
- **Project management** during all the procedure.

OUTCOME

Time-to-market optimization for the customers' registrations, as well as achievement of international expansion

As a result of helping our Client to choose the **right strategy** for each country, we enhanced the **time-to-market**.

Currently the Client is **consolidating its international leadership**:

- **More than 40 MAs obtained in 12 European markets.**
- **More than 25 MAs expected to be obtained by 2022**