

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.

RESULT

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