PRIMEVIGILANCE

An Ergomed company

CASE STUDY

Complex Local Project

Flexibility and availability of our local experts to work within a restrictive client project environment

Visual Snapshot

Product & Therapeutic Areas

- Biosimilar in cancer treatment
- Gx for CNS
- Gx for Women's Health

Background/Project Overview

- LCPPV/LCPRA/LCPQA/PRLS services
- Regulatory Intelligence
- Market launch by providing RA expertise in local territories

18

EU/EEA countries

Challenge

- 300+ Marketing Authorisations i.e. 100+ individual dossiers.
- Short timeline for submission of documents to the NCA, unclear official guidance regarding local requirements, local support essential.

Approach

- **Pre-Launch Meetings:** Definition of expectations, strategy and timeline.
- **Gap Analysis:** Assessment of requested local roles and the latest approved product information for compliance, Braille certificate, artworks design, national codes, latest approved product information, prioritization based on business strategy, target markets, Power of Attorney, supply chain, and commercial packaging.
- **Strategy:** Analysis of priority actions, required countries and roles, allocation of relevant experts. Development of a rapid launch plan focusing on business objectives; target markets, supply chain, and commercial packaging. Development of action items and timelines to achieve milestones.
- **Execution:** Flexible approach to meet the urgent request. Setting up the network of LCPs and PRLs in a timely manner as per client needs.

Result

Products were successfully launched on the market within agreed timeline.

Efficiency in merging the services already provided for one of the two affiliated stakeholders (MAH and their distributor).