


CASE STUDY:

Feasibility evaluation of obtaining OTC classification for two anti-inflammatory drugs

 **CLIENT SIZE** Medium Pharma

 **GEOGRAPHY** Global

 **THERAPEUTIC AREA** Anti-inflammatory drugs

CLIENT NEED

- ▶ The client had developed two anti-inflammatory drugs
The client needed support with:
- ▶ Feasibility evaluation about obtaining OTC classification
- ▶ Establishing a global development & regulatory plan
- ▶ Stepwise approach to obtain OTC classification
- ▶ Expansion to major non-EU markets worldwide involving local affiliates in market investigations

OUR SOLUTION

- ▶ Verify legal status (Rx/OTC) and indications focusing on key markets worldwide
- ▶ Evaluation of clinical / non-clinical documentation (reports, literature) for switch candidates in comparison to main competitor
- ▶ Identification of unique selling points
- ▶ Recommendations for measures to obtain OTC status (e.g. indications, dosing and other posology changes, clinical studies)

PHARMALEX VALUE TO CLIENT

- ▶ Three months of focused work on the project, enabled the client to focus on own capacity for core activities
- ▶ PharmaLex experts with long-term experience and regulatory know-how in the field of OTC switches
- ▶ Successful cooperation with local affiliates

DISCOVERY /
NON-CLINICAL

CLINICAL
DEVELOPMENT

MARKETING AUTHORIZATION
/ APPROVAL

PRODUCT
MAINTENANCE