excelya

Case Study

Type:	Geography:	Study Type:	Client:
Regulatory Affairs	Europe	Full Service	Generics Pharma Company

PROJECT TITLE: Regulatory Affairs Support

Objective:

The Client selected Excelya to act as the main contact point in Greece and Cyprus, to provide support on Regulatory Affairs procedures regarding Marketing Authorization submissions, product lifecycle maintenance and artwork review, and approval, and on Market Access activities.

Project Challenges:

1) Over 100 products/250 Marketing Authorizations (Centralized, MRP/DCP, National)

2) Delayed national approvals of variations, resulting in obsolete packaging and harmonization issues in the concerned countries

3) Distributor transitions planned in both countries, potentially impacting product market availability

Excelya Solutions:

1) Flexible team to adapt to workload

2) Diligent collaboration with Health Authorities for issues resolution

3) Thorough review and high-quality translation of product information to speed up national approvals

4) Effective management for simultaneous implementation of artwork changes in both countries

5) Regulatory intelligence addressing all aspects of distributor transitions

6) Effective coordination of all parties involved in corresponding company activities

Benefits for the Client:

* Holistic approach (regulatory, market access, company collaborations, national compliance) and minimum client business impact
* One point of contact - no turnover in project team for 4 years collaboration
* Positive company image with local Authorities
* Concise process flows- effective launch planning
* Smooth distributor transitions
* Subject Matter Expert availability

Client Feedback:

"Excellent collaboration"

"Always there and ready to support"

"We consider Excelya's employees as valuable partners"