Case Study: Transfer of Marketing Authorization in Argentina for a Biologic

Client
A UK based global specialty pharmaceutical company.

Products
An interleukin 6 antagonist for treatment of multicentric Castleman's disease

Product Categories
Biologic

Country of Interest
Argentina

Services Offered
- License Transfer
- GMP Certificate Update
- Update Label and Submission
- Lifecycle Management
- Local Representation

Client Situation

The Client is a UK based specialty pharmaceutical company that had acquired global license for a novel biologic, an interleukin 6 antagonist for treatment of multicentric Castleman's disease from a large pharma company. Client did not have a local presence in Argentina and was seeking a trusted partner to initiate license transfer in Argentina and act as its legal representative in Argentina.

GRP Solution

GRP team in Argentina has a decade of experience in obtaining successful approval for new biologics, transferring existing marketing authorization license between companies and managing life cycle of biologics in Argentina according to local regulations. GRP team provided the following services to the clients:

Application for License Transfer
- Preparation and submission of application for license transfer from licensor to licensee (Client) company
- Review and compilation of document as per ANMAT requirements
- Translation of documents in Spanish

Application for GMP Certificate Update
- Preparation and submission of application to update GMP certificate
- Submission of declarations as required

Label Update and Submission
- Update of label as per ANMAT requirements as part of license transfer process
- GRP Argentina was mentioned as local representative for Client on label
- Review and submission of revised artwork for submission

Local Representation
- Act as interface between Client and ANMAT
- Respond to ANMAT queries
- Manage compliance, relationship with distributors
- Manage product release, health authority audits
- Ensure quality and safety compliance

Product Lifecycle Maintenance
- Manage periodic product license renewals
- Prepare and submit amendments
- Prepare and submit period safety reports as applicable
- Act as point of contact for health authority queries and inspections
- All submissions performed in eCTD format

Keywords: biologic license transfer Argentina, biologic license transfer ANMAT, new drug license transfer Argentina, ANMAT new drug registration, local representative ANMAT, Argentina regulatory consultant, annual reports Argentina new drug, biologic registration ANMAT, ANMAT gmp inspection, label requirements biologic new drug ANMAT

Key Highlights:

- GRP was the preferred partner for client as a one-stop, end to end solutions provider for all regulatory services needed in Argentina
- GRP's experience with biologics and regional market insights helped client complete the license transfer activities in time and proceed with commercial plans to meet business objectives

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