ALTER PHARMA GROUP NV

PARALLEL IMPORT BUSINESS UNIT
REGULATORY AFFAIRS / MARKET ACCESS MANAGER

ABOUT OUR COMPANY

Alter Pharma is a Belgian group of pharmaceutical companies with headquarters in Anderlecht (Belgium) and offices in Ireland and the United States. Employing in total over 140 employees, the Group distributes a wide range of pharmaceutical products to pharmacies, wholesalers, hospitals and retirement homes. At the same time, Alter Pharma is a global player on the generics market, with around 15 molecules on the European and US market and a fully stocked pipeline of niche, complex and added value products.

Our values

Our talented staff daily work in accordance with our company values:

- We are proud of our entrepreneurial culture and foster open communication, mutual respect, professionalism and efficient decision-making and we believe that our multicultural organisation is one of our most important competitive advantages.
- We believe that timely and well considered decisions as a response to emerging opportunities and ideas is the key to our success.
- We believe that the success of the company lies in the competence, dedication and motivation of each of our employees.
- We believe that freedom returns flexibility and empowerment returns commitment.

We are currently looking for a talented Regulatory Affairs / Market Access Manager PI to help us proactively managing the lifecycle of the medicinal products. The successful candidate must have proven skills in Regulatory Affairs and has at least 8 years relevant experience in RA in the pharmaceutical industry amongst which Market Access Area (regulatory, product pricing, listing, reimbursement and/or HEs).

You will be responsible for all areas within RA and Market Access.
You will report directly to the companies' Group QA Director and will be based in Anderlecht, Belgium.

The job description

The Regulatory Affairs / Market Access Manager PI undertakes full responsibility:

Regulatory Affairs

- Lead the RA team, develops the Regulatory Communication Strategy, report the Key Performance Indicators of the team and identify continuous improvement opportunities
- Represents RA in cross-departmental meetings and is responsible for management and follow-up of RA related priorities and questions
- Helps with due diligence and integration of new product developments/new product introductions

- You are responsible for the preparation of the dossier, submission of license requests, renewals and variations towards the local health authorities.
- You are responsible for the maintenance of the RA database, monitoring start / stop commercialisation, communicating product availability or shortages with the FAGG, overall fulllife-cycle of the oriduct.
- You give final approval for artwork or comment where needed.
- Keeps a going awareness of new and developing regulations in the respective field of expertise.

Market Access

- You are responsible for all aspects related to price and reimbursement.
- You communicate and agree prices with the ministry of economic affairs and price requests with the ministry of social affairs (RIZIV) depending on the registration status and pricing structure.
- You are the primary contact person with the RIZIV regarding the follow-up of the process and adjustment of the price positioning (trimestrial check), follow-up and interpret saving measurements.

People Management

- Responsible for people management, coaching the RA PI team and look after the further development of the expertise within the team by education and training.

The Regulatory Affairs / Market Access Manager PI will act according to the companies' mission, vision and strategy.

Your professional profile

The successful candidate has a master degree in pharmaceutical sciences, engineering, biochemistry, chemistry … or equivalent through experience and have at least 8 years of relevant experience in RA in the pharmaceutical industry.

You have good knowledge of the relevant European regulations for manufacturing of pharmaceutical products, as well as good knowledge of manufacturing process for injectables and tablets. Knowledge of and experience in FDA regulations is an asset

Your abilities

- You are a self-starter and capable of working autonomously and efficient
- You are a clear communicator and have change management skills
- You drive for performance (fast decision taking, positive, courage, curious, connected)
- You have eye for detail but still being able to keep the holistic view. You are flexible and able to work with deadlines.
- You have a balancing entrepreneurial spirit with structure – willingness to adapt to shifting or competing priorities

- You empower people, look for alignment, teamwork, priority setting, trust, open communication
- You speak and write fluently Flemish. Other languages such as French, German and English are an asset.

For more information about our company, please visit www.alterpharmagroup.be. Motivation letter and CV can be sent to recruitment@alterpharma.be.