Management of the geographical roll-out of a change for several products registered in Europe & the Rest of the World

A pharmaceutical company contacted BlueReg to help them manage the change of address of the Marketing Authorisation Holder (MAH). In Europe, they had several products registered via centralized procedures (CP) and several products registered via Mutual Recognition Procedures (MRP). They also had more than 200 Marketing Authorisations all over the world (including USA & Canada).

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Challenges

- One of the main challenges was to set up the global strategy to change the address of the MAH in a dedicated timeframe for several products registered in Europe and in the rest of the world countries.

- Furthermore, in Europe, this change is a type IAIN variation. This immediate notification variation must be submitted within 14 days after the implementation of the change. When the company contacted BlueReg, the formal document in which the new address is mentioned (proof of establishment) to start the variation submission in Europe was not yet available.

BlueReg support

Regulatory Affairs

BlueReg was selected for its recognized expertise in all types of post-authorisation activities of medicinal products registered worldwide.

A dedicated team of consultants in Regulatory Affairs was assigned to this project.

The team was accountable for the following activities :

- Identify the impact of the change of address on mock-ups, Product Information (PI), and batch release site, as needed.

- Provide the global regulatory strategy to optimize the submission of this variation/notification in Europe and in the Rest of the World.

- Coordination of local country requirements for the submission

- Estimate the global fees amount

- Prepare additional documents (cover letters, letter of authorization, local application forms, mock-up...)

- Request of Certificates of Pharmaceutical Products (CPP) and legalisation, as required

- Submission of the variation/notification to the different Health Authorities

- Coordinate the implementation dates with the production sites

Supply Chain

-Preparation and validation of mock-ups

Achievements

- Global regulatory strategy provided with a synthesis of local regulatory requirements
- Notification to local Health Authorities
- Request and legalisation of CPPs
- Submission of variation/notification files, with additional country documents, to Health Autorities all over the world in accordance with agreed timelines
- Request and legalisation of CPPs