Regulatory support for the market launch of a medicinal product assessed through the centralised procedure

A company entrusted BlueReg to support them to prepare their first local market product launch in Europe, to allow the patient to obtain the medicine at the earliest point possible.

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Challenges

The project brief was to provide the regulatory support for Europe local market launches of a medicine assessed through the centralised procedure with the following constraints:

- First product launch in Europe for the client with no complete local affiliate set up in all European countries where market launch was planned.
- Additional challenges linked to the tight timelines for the patients suffering from a life-threatening pathology to obtain rapid access to the medicine.
- Simultaneous coordination of regulatory requirements for European countries including serialisation and local language labelling requirements.
- Interaction with multiple client stakeholders from manufacturing, logistics, regulatory, quality and pharmacovigilance.
- To optimise the sequence of launches with a market packaging strategy to avoid multiple country packs as far as possible.

BlueReg support

BlueReg provided a dedicated team of consultants with the appropriate expertise to fulfil the regulatory requirements and meet the client's expectations.

First step of the launch sequence: Early Access Program (EAP)

- Assess specific local requirements for such a programme to provide full regulatory support for European countries and finally to compile a report on regulatory requirements by country.
- Extend this regulatory support for a geographical roll out in the Rest of World.
- Support the different client's departments to understand and implement these local regulatory requirements

Second step of the launch sequence: the transition phase from EAP to commercial launch

- Packaging transition from EAP to full commercial launch in Europe with market requirements was completed.
- Support for the coordination of the launch sequence was provided
- Commercial launch: full market requirements for European countries was provided in addition to the EAP requirements.
- Optimisation of the market launch roll out in terms of shared packs considering the full constraints such as language, serialisation, local pictogram and local code etc.
- Managed and planned artwork changes carefully within the lifecycle activities.
- Supported the artwork packaging team / supply chain to deliver the product on time to the patients with timely responses to ad hoc requests.

Achievements

- The BlueReg team provided the full requirements for EAP in the countries of interest and supported the client with the correct packaging to use.
- The BlueReg team provided the full requirements for real commercial launch and advised how to successfully undertake the transition between EAP and commercial launch.
- The BlueReg team provided recommendations in term of pack simplification taking into account serialisation and language constraints.
- The BlueReg team supported the client during the registration of the European Medicines Verification Organisation (EMVO) and each National Medicines Verification Organisation (NMVO) to be compliant to the Falsified Medicines directives (FMD 2016/161 EC).
- Project scope extended to include the management of the local market launches in some European countries working with the client project teams.