Case Study

Exploitant services for MAA product

About PharmaBlue « Exploitant » establishment

PharmaBlue is part of the BlueReg family, an integrated service within the global european regulatory affairs consulting group. PharmaBlue is authorized by ANSM in France as an "Exploitant" establishment.

- Supports pharmaceutical companies for the marketing in France of their medicinal products which have been granted
  - an early access authorization
  - or a marketing authorization (MA)
- Medium / long term partner providing Exploitant services to clients for fast market access in France of their approved medicines (Orphan or unmet medical need)

Exploitant status in France

- Foreign companies seeking to enter the French market must have an **exploitant**, which is a very specific role, with no equivalent in the EU regulations (Public Health Code R. 5124-2 3).
- The **exploitant** is the entity holding most of the responsibility for ongoing obligations relating to the use of a marketing authorisation in France.
  - The sponsor will be the marketing authorization holder ('MAH')
  - PharmaBlue will be the **Exploitant**
- The **exploitant** needs to have & maintain
  - a pharmaceutical establishment license, that is subject to authorization by the ANSM (French competent authority)
  - a qualified person, called a Chief Pharmaceutical Officer (CPO)
  - a local qualified person for Pharmacovigilance

Role & Responsibilities of the CPO

- About the «Exploitant» Chief Pharmaceutical Officer (CPO):
  - French law places pharmaceutical responsibility in the hands of a named person, the Chief Pharmaceutical Officer ("Pharmacien Responsable").
  - This status is specific to France and derives directly from the pharmaceutical monopoly
  - The presence of a CPO is required in all pharmaceutical companies in France, irrespective of their activities.
  - The CPO responsibilities are broader than those of the "Qualified person" defined at European level.
  - The concept of responsibility is very important, and it is important that it be visible in a company organization chart with mention of the hierarchical links and delegations:
    *Pharmacist Manager, Interim Lead Pharmacist in the absence of the Chief Pharmacist, Assistant Pharmacists and Delegates.*His personal responsibility is engaged as a guarantor of the quality of the medication and the safety of the patients.

Exploitant services

As described in art R 5124-2 of the French Public Health Code

Distribution

Overlooking activities on the French market in close collaboration with the MAH, the manufacturer and the distributor

Quality

- Review and approve local artworks for printed packaging components
- Handle local product complaints and batch recalls,
- Review of Annual Product Quality Review
- Monitoring of Stock

Med Info & Advertising

- Handle medical info requests with 24/7 support service
- Reply to HCPs and patient questions
- Process for managing SmPC updates
- Validation, Management and Archiving of promotional Material

PV

- Local contact person for PV (Art.R5121-164)
- Management of local PV, Supporting local submission of Periodic Safety Update Reports (PBRERs) and other safety documents and ensure compliance with local requirements

Timing

The set up and onboarding phase to implement all processes (Manufacture, Quality, PV, Medinfo) and define all roles and responsibilities of the different stakeholders for PharmaBlue to become Exploitant, will take up **to 3 months.** This depends mainly on the fluidity of interactions between PharmaBlue and its client.

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Any questions ? **Contact-us.**

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