White Paper

Early Access Programs 2022

5 common mistakes companies face when navigating French Early Access Programs

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01 Planning from the early stage

The timing of EAPs (early access programs) is critical. The ideal timing for implementation is usually around 12–18 months prior to launch. Typically, EAPs involve products that are in Phase III, although planning can begin during Phase II, and should include all relevant stakeholders where possible. The planning element is absolutely essential and should be factored into the timing, allowing for time to prepare documents and contracts, assemble educational materials and establish treatment criteria.

Actual timing and advanced preparation are important to ensure the EAP runs smoothly and that the patients can benefit as early as possible.

02 Not enough European /French resources available

There is also the concern of available resources at the EU and/or French country level to manage early access programs process; this necessarily has an impact on the planning, but also on the submission time once companies have started the project (we usually foresee 3 months of preparation in our estimates, and we generally assign 6-7 consultants working on the early access dossier).

Indeed, approval process of EAP is specific to France, with a detailed and standardized dossier to be prepared and submitted. The submission and assessment process requires regular interactions with the appropriate authorities; The French National Authority for Health (HAS) and Competent authority (ANSM).

EAP management requires French speakers to deal with prescribing physician(s), pharmacists, hospitals, authorities etc., ... Furthermore, daily management of early access program can be time consuming, with numerous administrative steps

03 Partner with a «low-cost» Exploitant

French regulatory authorities require companies to have an « Exploitant » authorized and established in France to manage any early access program. Under the French legal framework, an operator that wishes to market a medicinal product from and in France should hold an Exploitant status or partner with an Exploitant. The Exploitant operator is one of the pharmaceutical establishments authorized and regularly inspected by ANSM.

Many of our clients have faced this issue as they had selected their previous Exploitant partner based on pricing considerations. We strongly recommend having in mind that Exploitant responsibilities and activities are extremely demanding, especially if you are looking to distribute innovative products.

Therefore, you need to choose an Exploitant partner that truly understands your technology and most importantly has a flexible approach to be able to support you along the way.

04 Early Access Programs – Differences in Regulation and Implementation

While the name of EAPs varies by country, there are two main types of early access program in Europe; Compassionate Use Programs (CUPs) and Named-Patient Programs (NPPs). Both of these differ in certain ways to typical Expanded Access Programs in the US:

Compassionate Use Programs (CUPs)

A CUP is the most similar to the typical US Expanded Access Program. A medicinal product is made available for compassionate reasons to a group of patients in a selected clinic or hospital which treats patients with a serious debilitating disease, or where patients whose disease is considered to be life- threatening and who cannot be treated satisfactorily by an authorized medicinal product receive care.

Named-Patient Programs (NPPs)

NPPs involve pre-approval access to drugs in response to requests by physicians on behalf of specific, or "named", patients before those medicines are licensed in the patient's home country. Whereas CUPs (and Expanded Access Programs in the US) allow physicians to offer the drug to several patients who fulfill the criteria, NPPs are limited to the requested named patient or patients only.

Differences in the regulatory landscape of the EAPs in EU are more challenging to implement than in the US, therefore understanding the process needs to commence early on in the project.

05 Changing regulations that need to be monitored

In 2021, in the context of the French social security system's financing law, the procedure for temporary authorization for use (ATU) and exceptional reimbursement of medical products was modified, to simplify the schemes that permit early access to new drugs. This simplification enriched patient access by making the schemes more attractive to companies that are developing innovative medicine and have a multifaceted understanding of the guidance in order to navigate through the procedure and optimize chances of success.

Furthermore, the pharmaceutical industry has been thriving in France for a number of years, and the country is now home to over 200 major pharmaceutical companies or affiliates. With this significant growth comes new regulatory changes that will impact many biopharma organizations interested in launching into this market. For those not prepared, these steps can be extremely difficult without outside support from third party providers like BlueReg.

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Any questions ? **Contact-us.**

- contact@blue-reg.com
- www.blue-reg.com