White Paper

Early Access Programs 2022

5 must-know for US biotechs looking to run Early Access Programs in France

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01 Regulatory Constraints - the Exploitant

French regulatory authorities require having an « Exploitant » authorized and established in France to manage early access programs. Under the French legal framework, an operator that wants 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 (French competent authority).

02 Financial and Resources Constraints

Tangible investment is required if you want to setup your French affiliate by yourself, particularly so early in the access pathway (set-up with local health authority, recruitment of staff, partners identification). Furthermore, internal resources are often fully dedicated to FDA and/or EMA submission in parallel to EAP (early access programs) request/management.

03 Administrative and Management Constraints

Approval process of EAP is specific to France, with a detailed and standardized dossier to be prepared and submitted. Submission and assessment process requires regular interactions with Authorities, HAS (Haute Autorité de Santé) and ANSM (Agence nationale de sécurité du médicament et des produits de santé). EAP management requires French speakers to deal with prescribing physician(s), pharmacists, hospitals, authorities... Furthermore, Daily management of an early access program is time consuming, with numerous administrative steps.

04 New regulations in 2021

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 medicines but requires a deep understanding to navigate through the procedure and optimize chances of success.

05 French fast evolving regulations

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

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Any questions ? **Contact-us.**

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