



PharmaBlue
A ► PHARMALEX COMPANY

Drugs Eligibility criteria for early access programs in France



The drug must answer to all early access eligibility criteria

- Concerns the treatment of serious, rare or disabling diseases, when no appropriate treatment available
- Start of the treatment cannot be postponed
- Efficacy and safety of these drugs are strongly presumed from the results of therapeutic trials
- Drugs are presumed to be innovative, in comparison to a possible clinically relevant comparator

French regulatory authorities require having an « Exploitant » authorized and established in France to manage an early access program.

- 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).