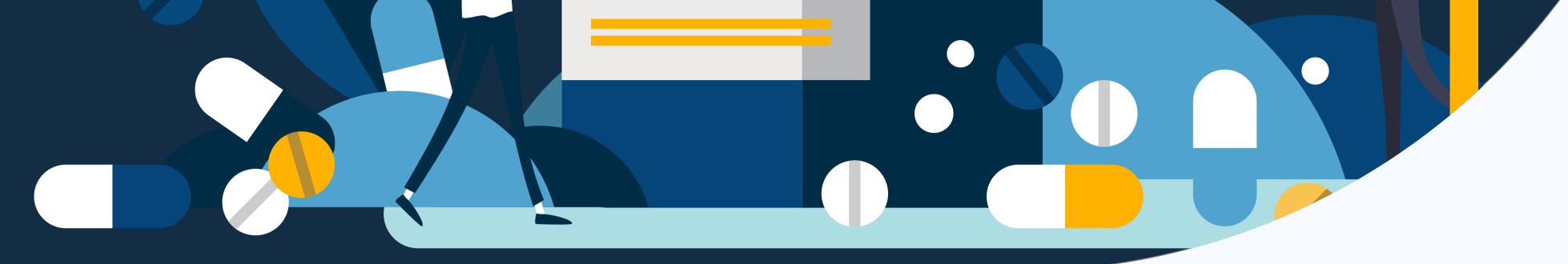


Drugs Eligibility criteria for early access programs



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).