

# EARLY ACCESS: HOW IT HAPPENS AND WHO'S INVOLVED.

## Patient

For a patient with a life-threatening or seriously debilitating condition, obtaining a medicine through early access routes may become relevant if all other treatment options have been exhausted.

## Clinician

A clinician determines a specific medicine may be an option for their patient, but it is not available through the usual routes. Both clinician and patient are willing to explore early access.

## Pharmacist

The pharmacy team processes the clinician's request. They complete the necessary importation or regulatory steps.

## Regulator

If the local regulator's conditions are met, the relevant regulations can be followed to import the unlicensed medicine for treatment use.

## Specialist Provider

Specialist providers can manage eligibility, importation, quality control, data collection and logistics to ensure the medicine is safely, efficiently and compliantly supplied.

## PATIENT ACCESS IS ACHIEVED.

# CLINIGEN



## Patient Groups



## Medicine

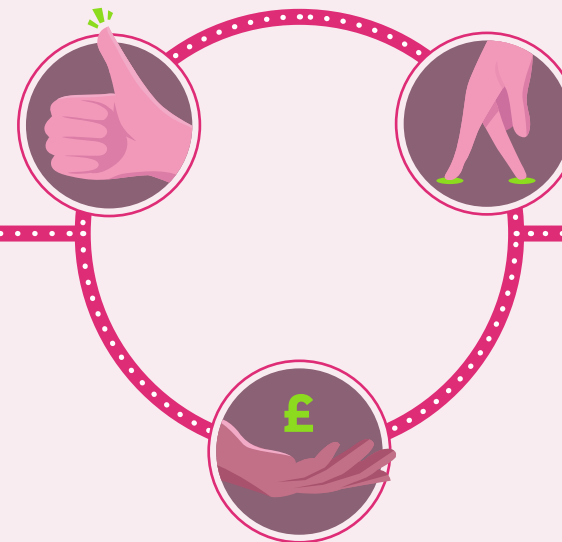
There is a medicine with supply available to meet demand, but it is not licensed where a patient resides, nor are any clinical trials involving the medicine available to the patient.

## Data

Data exists to support the benefit:risk ratio of the medicine, to the satisfaction of company, clinician and regulator.

## Industry

A company decides it will allow early access to its medicine, within the boundaries it has set. It has the budget and resources to deliver, whilst navigating complex demands.



## Funding

Sometimes medicines are supplied free of charge, but where the medicine is charged for, funding needs to be secured from the local healthcare system, or alternative funding sources.



## Patient Groups

Patient groups can support the community, engage key stakeholders and promote the interests of patients at all stages of early access.