

FRANCE

Direct Access Scheme for innovative treatments

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Améliorer l'accès aux médicaments innovants : l'expérimentation « Accès direct »

A pilot project started in May 2023

Convention lance

At a glance

Since May 2023 dossier submissions for new treatments evaluated by the HAS with a major or important SMR and at least ASMR IV may benefit from immediate reimbursement at free price given the treatment is at least 12 mths available to patients. Final decision on price and reimbursement conditions after 12 mths.

Who may benefit

Any product that received an ASMR of V will not benefit from the new scheme. Though still more than 1/3 of dossiers may have a chance to participate.



≈ 39%

of all submissions for new treatments to HAS received an ASMR I-IV in 2021 - an indicator of how many submissions may be entitled



≈ 19%

of all submissions for new treatments in 2021 received an ASMR IV and maybe the biggest category to benefit

SCHEME



1

Assessment by the Commission de la Transparence
Submission of the dossier to HAS. Products rated with an SMR (service médical rendu) of major or important and ASMR (amélioration du service médical rendu) at minimum minor (IV)

2

Reimbursement
Products will be immediately reimbursed after HAS decision at free price for a period of 1 year.

3

Price
Price, reimbursement conditions and rebates will be decided after one year. Additional data collection during the one year period is not foreseen.

CONDITIONS



- Not eligible for early access. Thus, innovative and expensive hospital medicines eligible for the so-called "en sus" list or community medicines not reimbursed elsewhere.
- SMR of major or important and ASMR of at least minor
- Treatment is available to patients for at least 12mths
- Final price may include additional rebates or payments from sécurité sociale

WHAT TO DO



The new scheme will be evaluated by the MINISTÈRE DE LA SANTÉ ET DE LA PRÉVENTION, but it presents an incentive scheme which can be a cornerstone of a market access strategy if prepared well.

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Prepare early to determine 'most appropriate' free price



Determine early impact on follow indications



Assess in time the evidence requirements to achieve at least an ASMR IV