HAS FRANCE'S EARLY ACCESS SCHEME BECOME MORE SELECTIVE? EVIDENCE FROM TEMPORAL TRENDS IN EARLY ACCESS AND SUBSEQUENT ASMR RATINGS

Gaugy P[1], Garibello Garcia D[1], Charrier P[1], Estival A[1]

[1]CEMKA, Bourg-la-Reine, France

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1. BACKGROUND

The French Early Access (EA) scheme aims to provide rapid access to innovative medicines before permanent reimbursement assessment. Subsequent Transparency Committee (TC) assessments allow comparison of EA decisions with clinical added value, measured by ASMR ratings.

2. OBJECTIVE

To assess whether changes in EA refusal rates were associated with closer alignment between EA decisions and subsequent ASMR ratings.

3. METHODS

Data source

Publicly available HAS data covering EA decisions issued between July 2021, following the implementation of the reformed French Early Access (EA) scheme, and May 2026.

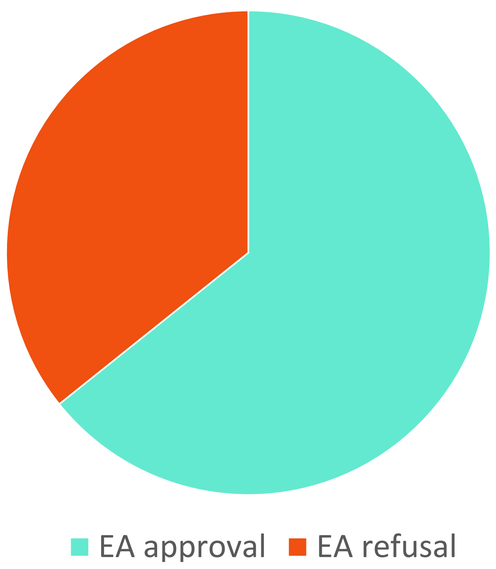
Inclusion criteria

All initial EA applications were included.

Data extraction and analysis

- Annual proportions of favourable and unfavourable EA decisions.
- Proportion of subsequent ASMR V ratings according to initial EA outcome and year of decision.
- Descriptive comparison of temporal trends in EA decisions and subsequent TC assessments.

4. STUDY SAMPLE



249 EA decisions:

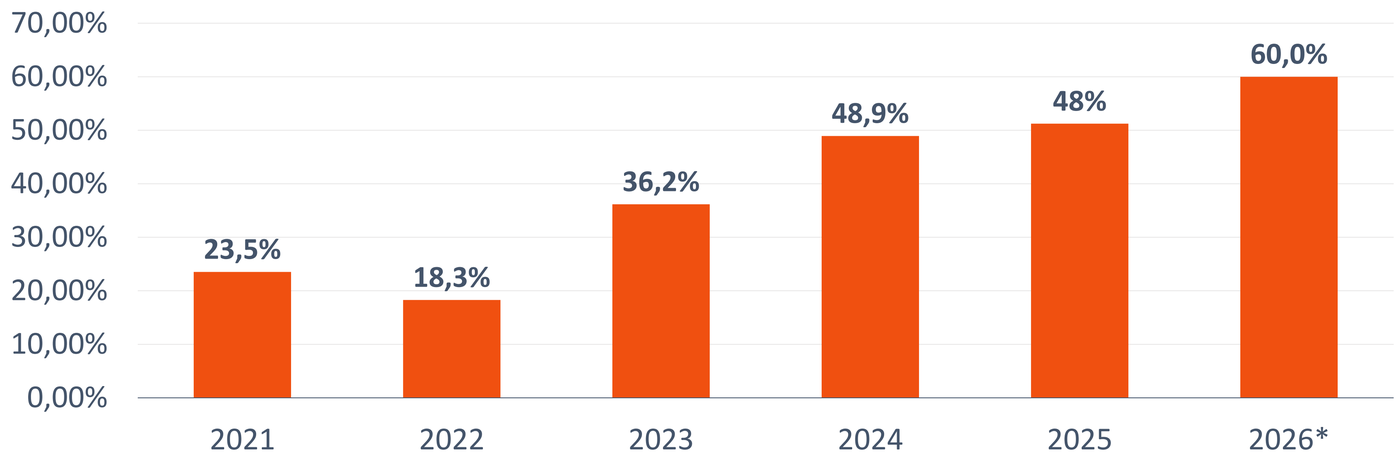
- **160 granted (64.3%)**
- **89 refused (35.7%)**

Subsequent TC assessment available:

- 144/160 granted EA decisions (90.0%)
- 65/89 refused EA decisions (73.0%)

5. EA REFUSAL TRENDS*

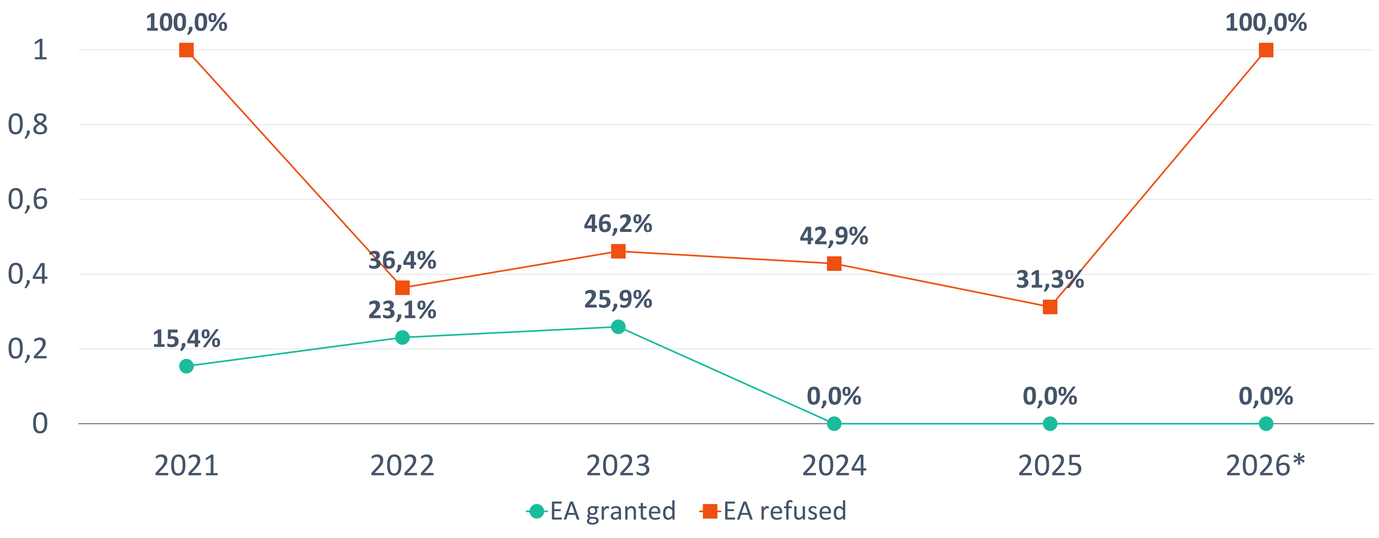
EA refusal rates increased overall, from 23.5% in July–December 2021 to 60.0% in January–May 2026. After an initial decline in 2022 (18.3%), refusal rates rose substantially in 2023 (36.2%) and 2024 (48.9%), remained relatively stable in 2025 (48.0%), and reached their highest observed level in 2026 (60.0%).



6. SUBSEQUENT ASMR V RATINGS*

Among medicines granted EA, the proportion subsequently receiving an ASMR V rating ranged from 15.4% to 25.9% between 2021 and 2023, but fell to 0% in the 2024–2026 cohorts with available TC assessments.

In contrast, ASMR V ratings remained frequent among medicines refused EA (31.3%–100.0% across years), suggesting greater consistency between favourable EA decisions and subsequent recognition of clinical added value in recent cohorts.



2021: July–December; 2026: January–May. Only initial EA applications were included; renewals and reassessments were excluded. Subsequent ASMR analyses were restricted to applications with an available TC assessment.

7. INTERPRETATION AND LIMITATIONS

Interpretation

- The proportion of ASMR V ratings among medicines granted EA declined in recent cohorts, reaching 0% between 2024 and 2026 among products with available subsequent TC assessments.
- In contrast, ASMR V ratings remained frequent among medicines refused EA, ranging from 31.3% to 100% across the study period.
- These findings suggest an increasing ability of EA decisions to distinguish products subsequently recognised as providing added clinical value.

Limitations

- Recent EA cohorts have had less time to undergo subsequent TC assessment, meaning that available ASMR results may not be representative of all medicines granted or refused EA.
- The number of subsequent TC assessments was limited in some annual subgroups, particularly in 2026.
- Descriptive analyses do not establish a causal relationship between EA refusal rates and subsequent ASMR outcomes.

8. CONCLUSION AND KEY TAKEAWAYS

The French EA scheme showed an overall increase in refusal rates between July 2021 and May 2026, although substantial year-to-year fluctuations were observed.

Among medicines granted EA, the proportion subsequently receiving an ASMR V rating declined markedly in recent cohorts, suggesting greater consistency between early access decisions and subsequent recognition of clinical added value.

However, these findings should be interpreted cautiously given the incomplete follow-up of recent cohorts, particularly in 2026.

1. EA refusal rates increased overall between 2021 and 2026.
2. ASMR V was observed after EA approval in assessed 2024–2026 cohorts.
3. Recent EA decisions suggest improved alignment with subsequent HTA outcomes.
4. Incomplete follow-up and small samples warrant caution.



EA: early access. TC: Transparency Committee. ASMR V: no clinical added value.

COI: Garibello Garcia D, Gaugy P and Charrier P are employees at CEMKA, one of the first French consulting firms in the field of evaluation of products, programs and organizations in Health. The study was not sponsored.