From French early access to reimbursement: How do prices shift post-HTA?

Putnam Inizio Advisory

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Introduction

- The French early access (EA) programme, introduced in 2021, provides patients with serious or rare untreatable conditions earlier access to innovative medicines, while maintaining budgetary sustainability through price adjustments (1).
- While EA prices (EAP) are freely set by the manufacturers, the final negotiated list price (NP) is established through negotiation with the pricing committee, considering several factors such as the clinical added benefit, comparator prices, and European reference pricing.
    - EA accounts for significant pharmaceutical spending, with net expenditure (before rebates) on EA products increasing from €146 M in 2021 to €637 M in 2023 (2).
- Sales made during EAP are later reconciled through mandatory rebates, including adjustments for sales volume and for the difference between the EAP and the NP (3). In addition, this NP may also be subject to confidential discount agreements (4).
- NPs of EA products will potentially face increased pressure in 2026, following the French health insurance proposal to cut prices for products classified as having minor (ASMR IV) or no added benefit (ASMR V) that drive the highest drug expenditure in France (2).

Objective

The primary objective of this analysis is to compare EAPs with post-reimbursement NPs in France and to examine how observed price differentials relate to ASMR levels.

Methods

- Drugs with terminated EA after reimbursement decisions, as of July 2025, were identified from the Ministry of Health database (5).
- EAPs were sourced from the Ministry of Health database, and NPs from the health insurance database (6,7).
- ASMR levels for indications covered in EA were obtained from the corresponding reimbursement reports available on the HAS website (8).
- EAPs and NPs were compared.

Results

- A total of 88 products with terminated EA after reimbursement were identified, with both EAPs and NPs available for analysis.
- Although EAPs were maintained for a small minority of products, in most cases NPs were lower than EAPs, highlighting the downward adjustment of prices after negotiations **(Figure 1)**.
    - NPs were lower than EAPs in 82% (72/88) of the products, with a median price reduction of 14.8% (range: 0.43% to 83.8%). More than half of these products (60%; 43/72) had ASMR level IV or V.
    - EAPs were maintained in 15% of products (13/88). Among these, 5 had ASMR III, 6 had ASMR IV (including 4 orphan drugs), 1 was an orphan drug with ASMR III/IV, and 1 had ASMR II/IV. The guarantee of European price levels for ASMR III products and for orphan drugs with ASMR IV may explain the unchanged prices in most of these cases.
    - NPs exceeded EAPs in only three cases: +2% and +5% (both ASMR IV) and +11% (ASMR III), all 3 products were indicated in rare or ultrarare conditions and assessed for their first indication.
- No systematic correlation was observed between the price reduction and ASMR level, though products with ASMR V often showed substantial decreases. The extent of price differences depends on the outcome of confidential negotiations, and could been influenced by several factors, including the prices of available clinically relevant comparators drugs and international reference pricing **(Figure 2)**.
    - For all products with ASMR V vs existing therapies (n=12), NPs were lower than EAPs: 83% (10/12) had a price reduction of 15% or greater and 25% (3/12) had a reduction of over 35%, reaching up to 84%.
    - The highest price reduction (i.e. 84% versus EAP) was observed in one case for selpercatinib 40 mg – a product granted ASMR IV/V for the treatment of non-small cell lung cancer and ASMR V for the treatment of medullary thyroid carcinoma. This reduction was likely driven by pricing benchmarks from comparator targeted therapies which had a significantly lower annual NP vs selpercatinib' annual EAP.
    - Among ASMR III or IV products (n=71), 62% (44/71) had unchanged or modest reductions of <15% of their EAP, while 3 had a price increase (+2%, +5, +11%).

Figure 1. Range of price differences (NP vs EAP) per ASMR levels

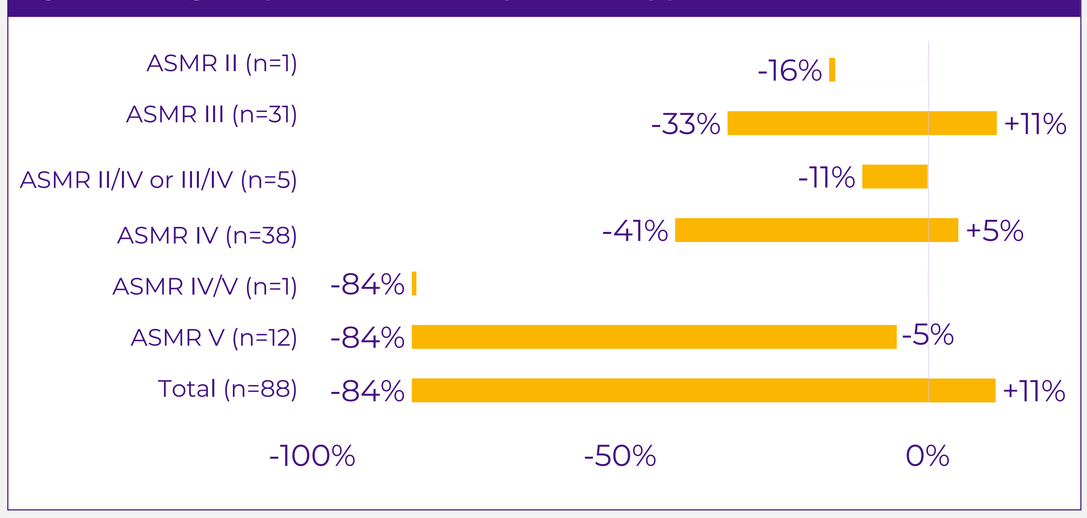
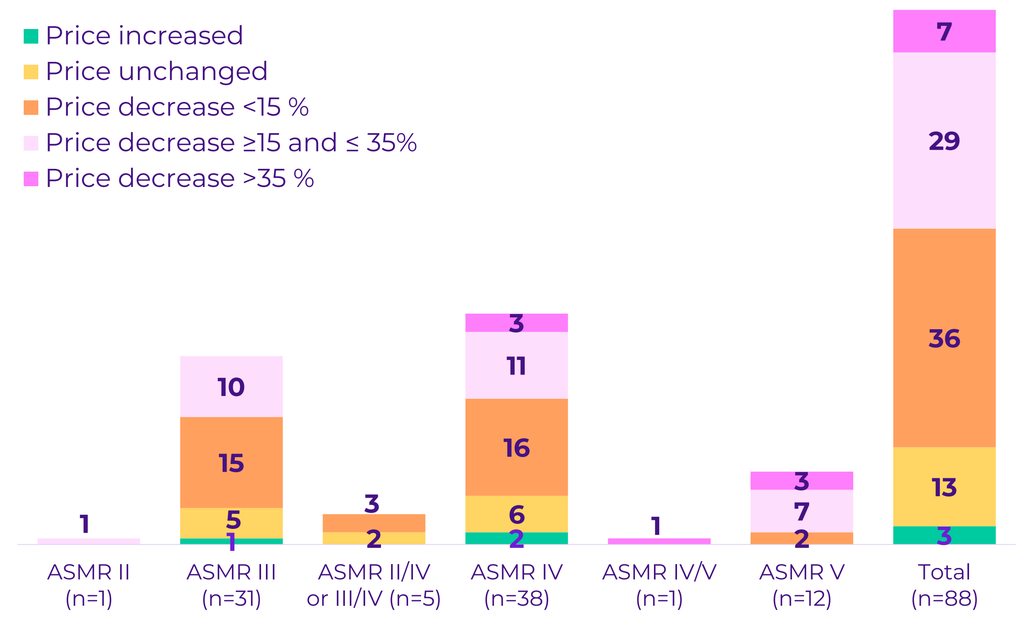


Figure 2. Overview of the distribution of ASMR levels and price differences



Discussion and conclusion

- This analysis confirms that maintaining the EAPs post-reimbursement negotiations is not guaranteed. Although manufacturers have the flexibility to set the EAP freely, in most cases (83%) the final NP is lower than the EAP, with reductions reaching up to 84%.
- Further price reductions are expected from 2026 in France, particularly for products with ASMR IV and V. Thus, manufacturers should adopt a cautious EAP strategy while anticipating forthcoming policy directions., taking into account the likely ASMR level, its impact on pricing, and comparator prices to mitigate substantial rebate obligations.

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Abbreviations

ASMR, added clinical benefit (amélioration du service médical rendu); ASMR II, important added benefit; ASMR III, moderate added benefit; ASMR IV, minor added benefit; ASMR V, no added benefit; EA, early access; EAP, early access price; NP, negotiated list price

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