Evaluating high-cost innovative medicines: A three-year analysis of pricing trends in France's Early Access Programme (AAP)

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INTRODUCTION

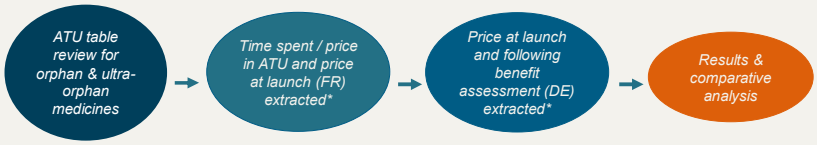
- On July 1st 2021, France's Social Security Financing Law implemented the Early Access Programme (AAP), replacing the existing ATU system. AAP and ATU terms are interchangeable, referred to hereafter as ATU during analysis.
- The AAP allows early access to innovative medicines which fulfil a significant unmet need in severe, rare or debilitating diseases.
- Applications to the AAP can occur:
  1. Prior to marketing authorisation
  2. Following marketing authorisation
- Decisions for AAP approval are typically issued within 90 days, with some exception to timelines depending on the product type[1].
- One benefit of the AAP for manufacturers is free pricing upon entry.
- However, price reductions are often observed following AAP exit since external reference pricing (ERP) is used in France to set innovative medicine prices[2].
- One of the key reference markets is Germany, which offers a free pricing period of 6 months for new medicines.
- If the final negotiated price is lower than the maximum fee charged during the AAP, manufacturers will face retrospective rebates.

OBJECTIVE

- This study compares the prices of innovative medicines during AAP participation and following exit over the past three years in France, to understand pricing dynamics, with a particular focus on reference pricing.

METHODS

- Early access authorisation (ATU) tables from June 2021 to February 2024 were reviewed, specifically for orphan and ultra-orphan medicines acknowledged by the EMA.
- For each orphan and ultra-orphan medicine identified, the following data was extracted: time spent in ATU (i.e., from entry to exit); price in France (in ATU and at launch); price in Germany (at launch and following initial benefit assessment).
- Extracted data facilitated a comparison of pricing trends in France's AAP with respect to prices in Germany.



*Launch prices extracted from Official Gazette (France) and G-BA website (Germany). German prices extracted for ten most-expensive medicines only.
Note: Medicines were excluded from analysis if price in ATU or Official Gazette was not available or published at the time of analysis.

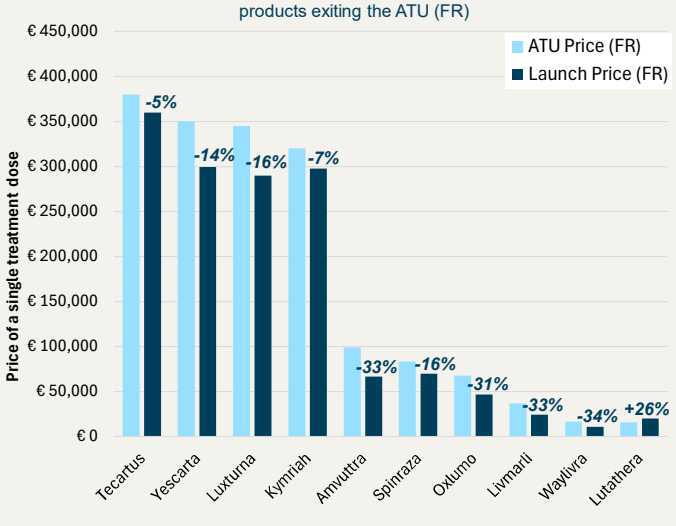
RESULTS

- Over the last three years, 78 orphan medicines have been listed on the early access authorisation tables in France.
- Of these, 39 have been fully reimbursed, with an average price reduction of 16% observed from ATU entry to exit. The average time taken from ATU entry to ATU exit was 845 days.
- For instance, the prices of the ten most-expensive orphan and ultra-orphan medicines exiting the ATU saw an average reduction of ~16% (**Figure 1**). In total, 27 of 39 medicines incurred a price reduction of more than 10%, 6 had a reduction of 0-10%, and 6 achieved an increase in price.
- Price reduction per pack following ATU exit varies per product and depends on the difference between ATU price versus launch price published in the Official Gazette **Table 1**, meaning manufacturers may be required to pay retrospective rebates following ATU exit.
- Prices for the ten most-expensive products following initial benefit assessment in Germany were reduced on average by ~27% since launch (**Figure 2**). France considers these reduced prices during ERP.

Table 1: Price reduction per pack for most-expensive orphan and ultra-orphan products exiting the ATU (FR)

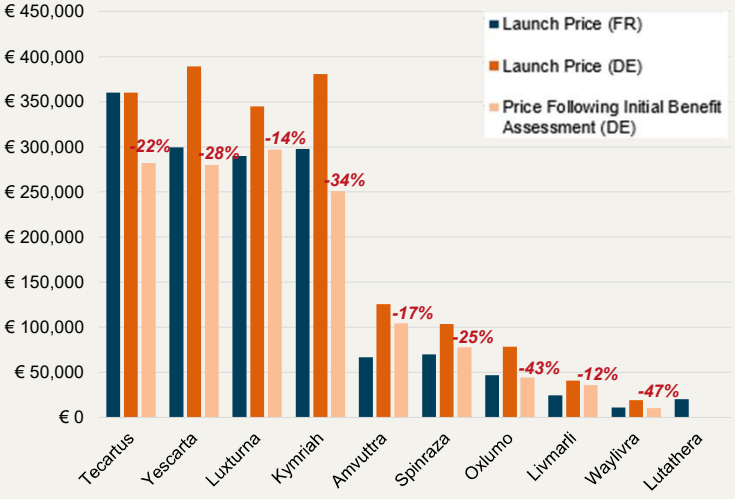
Brand Name	Price reduction per pack
Tecartus	-€20,000
Yescarta	-€50,500
Luxturna	-€55,000
Kymriah	-€22,334
Amvuttra	-€32,654
Spinraza	-€13,328
Oxlumo	-€20,973
Livmarli	-€12,268
Waylivra	-€5,647
Lutathera	+€4,175

Figure 1: Prices of the most-expensive orphan and ultra-orphan products exiting the ATU (FR)



% difference between ATU and launch price

Figure 2: Prices of the most-expensive orphan and ultra-orphan products at launch (FR & DE) and following initial benefit assessment (DE)



% difference between launch price (DE) versus price following initial benefit assessment

DISCUSSION

- The AAP (ATU) scheme in France provides opportunity for early patient access to innovative medicines.
- However, price reductions following AAP exit frequently occur, typically driven by referencing the negotiated price in Germany post-benefit assessment.
- As a result, manufacturers can be stung with retrospective rebates following AAP exit, if the price set during early access is largely different to the launch price.

CONCLUSION

- An attractive option for launching high-cost innovative medicines in France is the AAP. Despite flexible pricing, prices often decrease following AAP exit due to reference pricing, often focused on Germany.
- This analysis supports the importance of considering pricing implications in early access programmes as part of French Health Technology Assessment (HTA) strategy.

REFERENCES

1 HAS Website https://www.has-sante.fr/jcms/p_3340090/en/early-access-authorisation-a-positive-initial-report-and-refined-assessment-methods
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