

Utilization-Based Managed Entry Agreements: Is there a future for these arrangements across the EU4?

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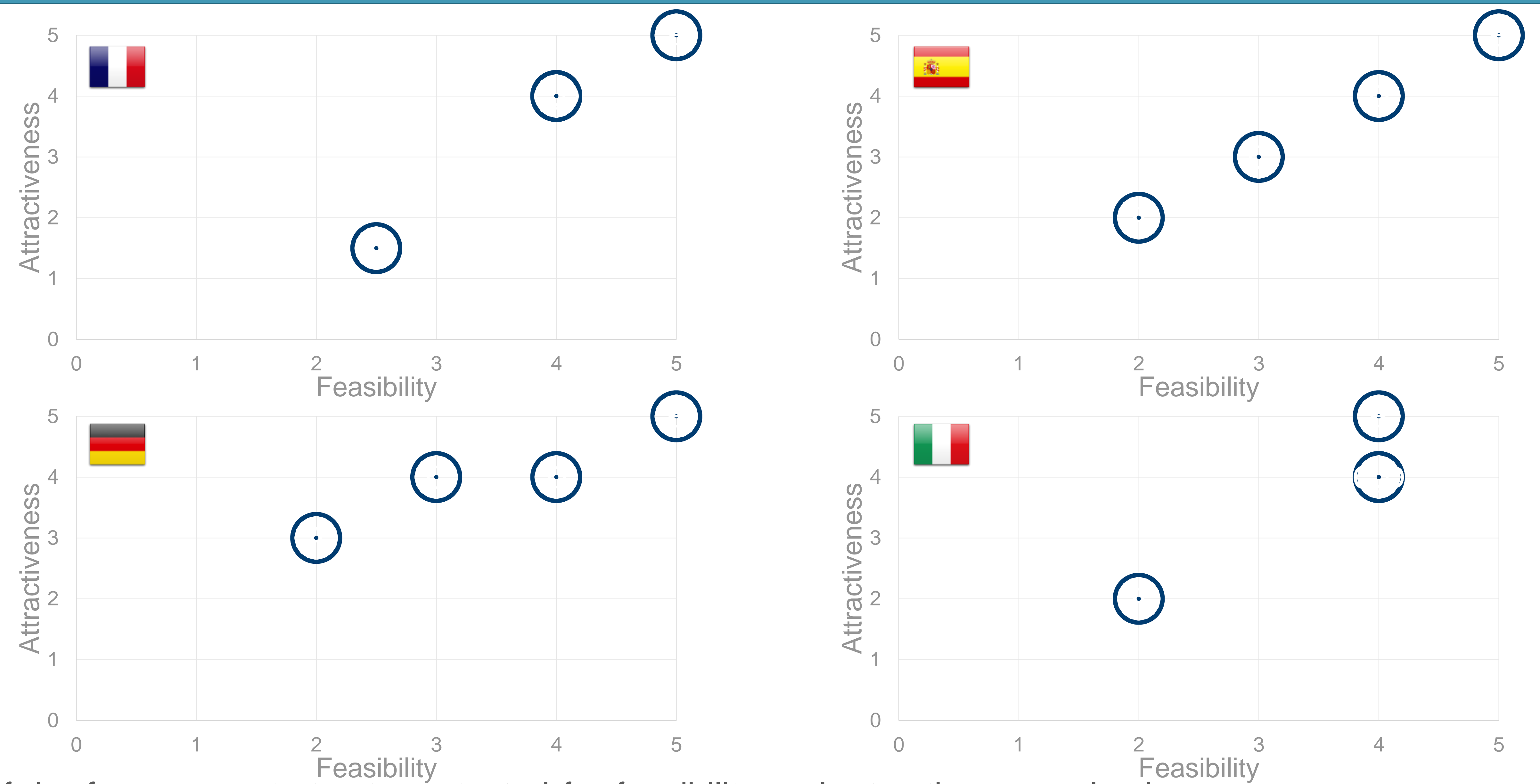
Objectives

- Many high-cost orphan and oncology agents adopt a type of managed entry agreement (MEA) for commercialization to help EU payers marry the clinical value with the financial costs of such therapies. In the US, some manufacturers launching high-cost drugs with weight-based dosing and/or a need for titration have used patient utilization adjustment (PUA) contracts to mitigate the risk of unpredictable costs associated with individualized dosing.
- We aim to understand what potential value EU4 payers assign to a PUA contract and how this compares to existing contract structures.

Methods

- We surveyed national payers from FR, DE, IT, and ES to understand the attractiveness and feasibility of managed entry agreements, including PUA, simple discounting, responder-driven outcomes arrangement, and event-based outcomes arrangements.
- Contract Definitions:
 - Patient Utilization Adjustment:** Rebate if the amount of product utilized by a patient exceeds an established threshold
 - Simple Discount:** Discount applied regardless of outcomes or utilization
 - Proportion of Responders:** Rebate based on the proportion of patients who respond to therapy
 - Event-Based:** Rebate based on the proportion of patients who undergo an event linked to treatment failure (e.g., liver transplant)
- Additionally, we asked about the top benefits and challenges of such agreements. Survey findings were supplemented with phone interviews for a deeper understanding of the insights.

Results



- Of the four contract structures tested for feasibility and attractiveness, simple discounts scored highest on average (attractiveness: 4.8/5; feasibility: 5/5) while PUA-style agreements scored the lowest (2.1/5).
- The main barrier of a PUA-style agreement was the preference to conduct such tracking at an aggregate level (similar to a budget cap), rather than at an individual level.
- While alternative outcomes-linked VBAs were viewed more favorably than a PUA, they still trailed simple discounting as they're easier to implement and track.

Key:

- A | Patient Utilization Adjustment
- B | Simple Discount
- C | Proportion of Responders
- D | Event-Based

Conclusions

- EU4 payers did not see viability in a PUA-style contract, opting to implement a simple budget cap in the event there is uncertainty around associated cost due to dosing variability.
- Payers generally prefer simple discounts, which are easily implemented; however, outcome-based contracts can create sustainable opportunities for manufacturers when launching agents that may command premium prices in a future environment where national payers increasingly demand demonstrated clinical and financial value.

Abbreviations: MEA, Managed Entry Agreement. PUA, Patient Utilization Adjustment.