Current and Future Trends in P&R Decisions of Oncology and Onco-Hematology Drugs in Spain: *A retrospective and forum discussion study*

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OBJECTIVES

> Understand the impact of different variables leveraged during the Spanish P&R process on companies' target price
> Understand future trends in innovative drug P&R decisions.
  - **Scope:** First negotiated indication of oncology and onco-hematology drug

METHODOLOGY

> **Data analysis**: Based on LGURM and TPRs, statistical analysis of hypotheses on the relationship between different variables and the Spanish price
  - The price was assessed based on the difference between the company target price (Germany) and the Spanish reimbursed price:

Impact on Target Price → Price at launch (free price) → **% Difference** ← Reimbursed price

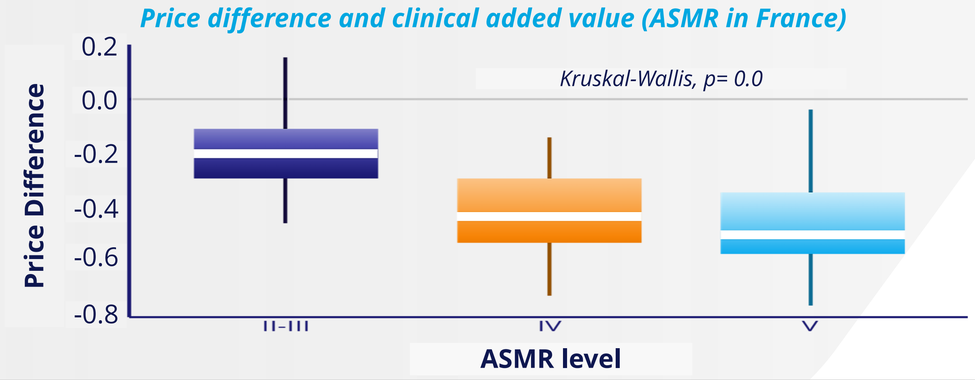
> **Primary research**: Results discussed in an expert forum to assess the improvement areas and future vision

RESULTS

HISTORIC OVERVIEW

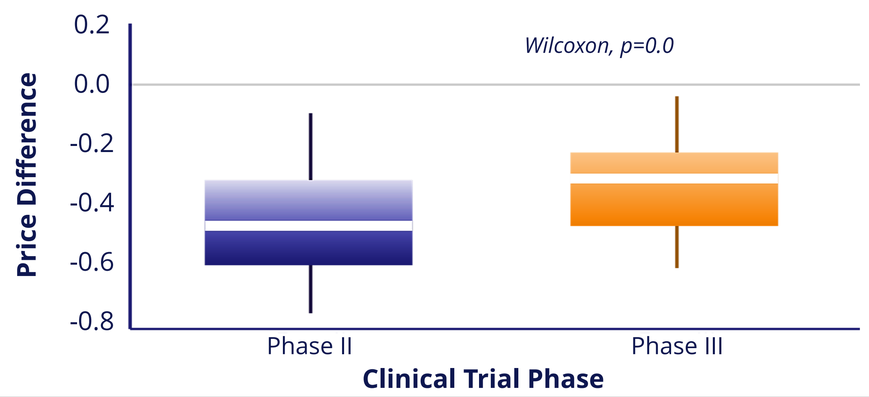
> **The clinical added value of reimbursed drugs (based on the ASMR in France[1]) had a statistically significant correlation with the price difference** *(p = 0.0)*, indicating that it is a key criterion for the P&R decision-making. Additionally, >70% of non-reimbursed drugs obtained non-added value rating (ASMR V), further validating the relevance of this criterion

Price difference and clinical added value (ASMR in France)



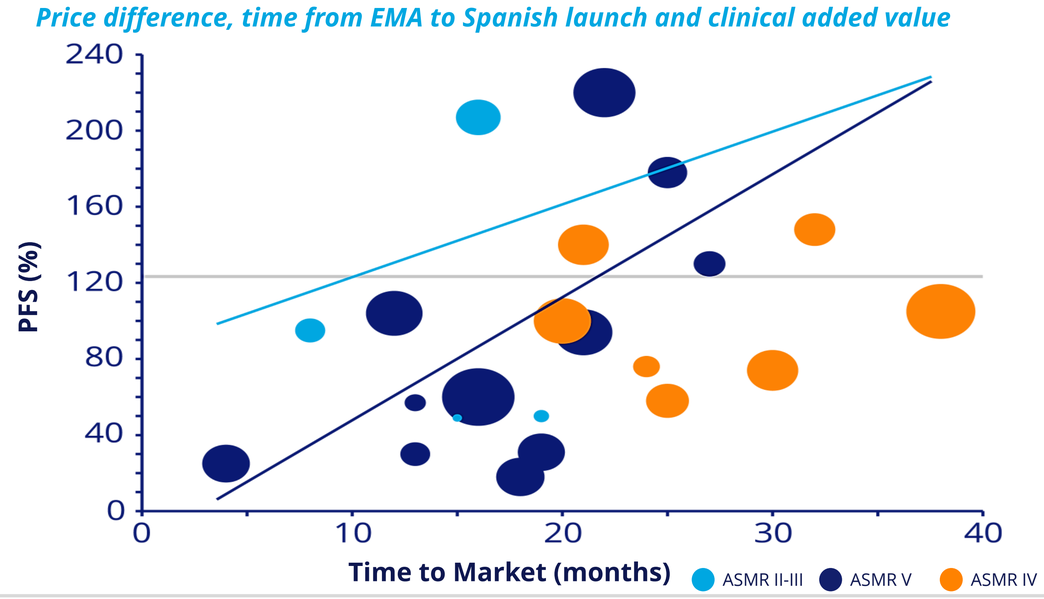
> The **clinical trial phase has** statistical significance (p = 0.0) with **the price difference**, indicating that evidence from a **phase II trial has a smaller price difference than that from a phase III**

Price difference and clinical trial phase



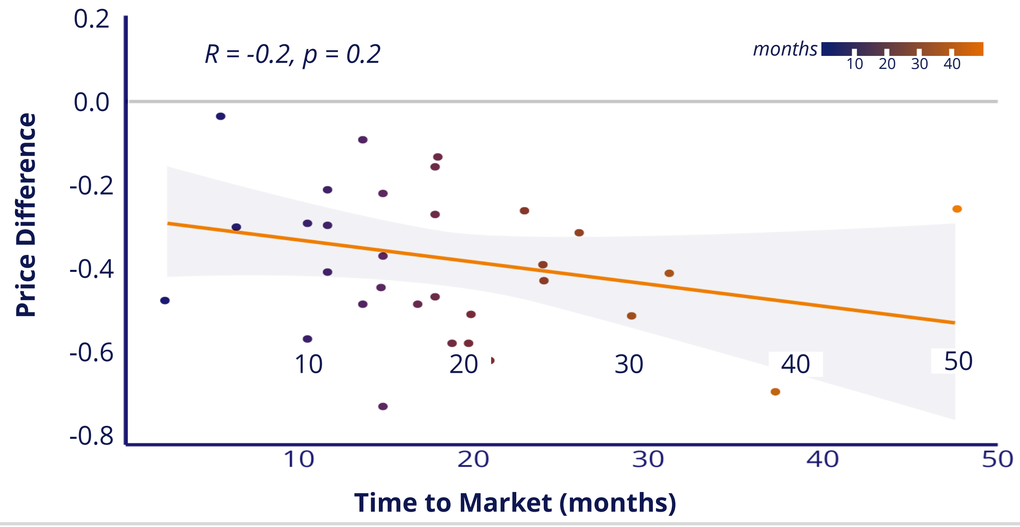
> **Clear value perception** (ASMR II-III or ASMR V) had **shorter times to market than drugs with minor improvement** (ASMR IV)

Price difference, time from EMA to Spanish launch and clinical added value



> The longer the **time from EMA approval to the launch in Spain, the greater the price difference**

Price difference and time from EMA approval to launch in Spain



> **ODDs** had a **smaller price reduction (-33%)** compared to non-orphan drugs **(-46%)**
> **2L or 3L positioning** had a lower **price reduction (-39%)** than those in **1L (-46%)**
> **No relationship** was observed between the price reduction and the **clinical trial design** (except for the phase), the **efficacy results** (PFS, OS, and ORR), or the implementation of **managed-entry agreements**

FUTURE VISION *(ROUNDTABLE DISCUSSION)*

A **standard, systematic, independent, and transparent approach** to assess a drug's added benefit (like the French ASMR or German AMNOG) should be developed to build a **predictable HTA framework**

1. Flexibility to accommodate drug-specific situations (e.g., precision medicine)
2. Broader perspective: evolve from an economistic approach (CEM, BIM) to a **social perspective**
3. **Direct incorporation of patients' perspective** through specific tools (such as PREMs and PROMs)
4. **Consistent inclusion of multistakeholders' perspectives** (patients, clinicians, pharmacists, managers, etc.)

CONCLUSION

> The **added clinical benefit** is a key criterion shaping reimbursed price in Spain, whereas the impact of other factors is not completely clear
> A **standard, systematic, independent and transparent approach** to drug evaluation based on their benefit (like the French ASMR or German AMNOG) should be developed to build a **predictable HTA framework**

Note: [1]ASMR in France is divided into five categories: ASMR I: innovative product with substantial therapeutic benefit, ASMR II: significant improvement in terms of efficacy and/or reduction of adverse effects, ASMR III: moderate improvement, ASMR IV: minor improvement, ASMR V: no improvement | **Abbreviations:** 1L: first line; 2L: second line; 3L: third line; ASMR: *L'amelioration du service médical rendu*; EMA: European Medicines Agency; LGURM: *Ley de Garantías y Uso Racional de los medicamentos*; ODD: Orphan Drug Designation; ORR: objective response rate; OS: overall survival; PREM: Patient Reported Experience Measure; PROM: Patient Reported Outcome Measure; P&R: pricing and reimbursement; PFS: progression free survival; TPR: Therapeutic Positioning Report.

REFERENCES

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