Understanding the Pricing and Reimbursement Outcomes of Advanced Therapy Medicinal Products in Spain

HTA323

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OBJECTIVE

> The objective of this study was to assess the key factors influencing the pricing and reimbursement (P&R) outcomes of Advanced Therapy Medicinal Products (ATMPs) in Spain.

METHODOLOGY

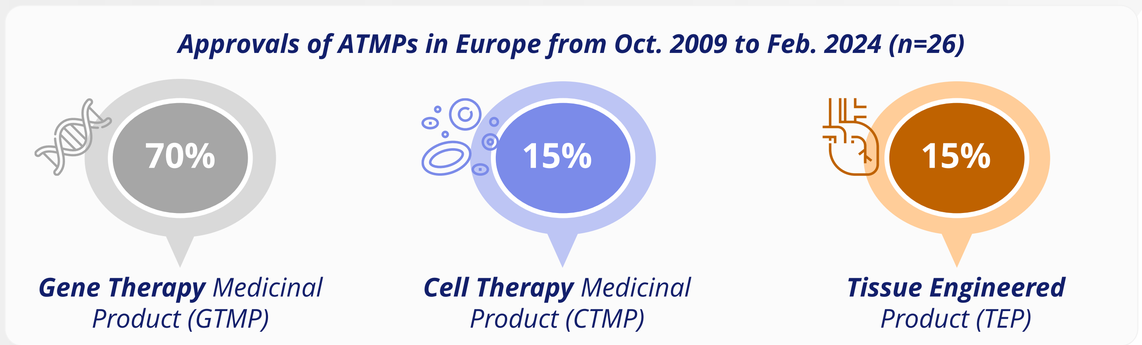
> Secondary research was developed to analyse the ATMPs approved in Europe from October 2009 to February 2024 that entered the P&R process in Spain, and how different factors could impact drug availability and timeframes[1,2].

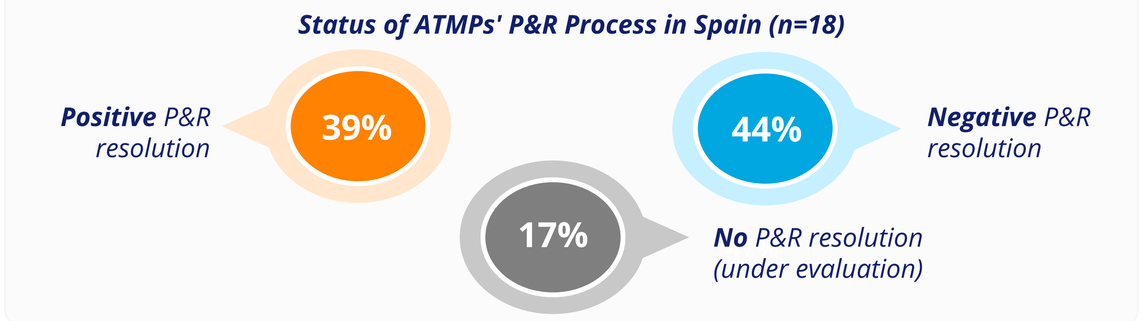
RESULTS

ATMPs Situation in Spain

> A total of 26 ATMPs were approved in Europe. Of these, **18 initiated the P&R process in Spain** [1,3]: 7 (39%) received a positive resolution, 8 (44%) a negative, and 3 (17%) were under evaluation (Figure 1[1,3])

Figure 1. ATMPs' Overview





ATMPs with a P&R Resolution in Spain (n=15)

> Most of the ATMPs were **gene therapies** (80%), with an **orphan designation** (80%), and were authorised **under exceptional circumstances or conditional approval** (87%) [1,3]

> The approval was based on **phase I/II** (47%) or **phase III** (40%) clinical trials, predominantly **open-label** (94%), **non-comparative** (87%), and **non-randomized** (80%) [1,3]

> A big proportion were **antineoplastic/immunomodulatory agents** (53%), evaluated with **hard outcome measures** (60%) and as a **first-line treatment** (54%) [1,3]

> Among the **reimbursed therapies** (n=8), all of them were subject **to price discounts** (range: 4-38%), and 86% had **restricted access** to the reimbursed indication and payment-by-results agreements [4-6]

Analysis of Reimbursed and Non-Reimbursed ATMPs in Spain

> Comparisons between reimbursed and non-reimbursed therapies reveal the following points (Figure 2 [1,3]):

a) All reimbursed therapies were granted **orphan designation**, indicating their focus on rare conditions, compared to 63% of the non-reimbursed therapies

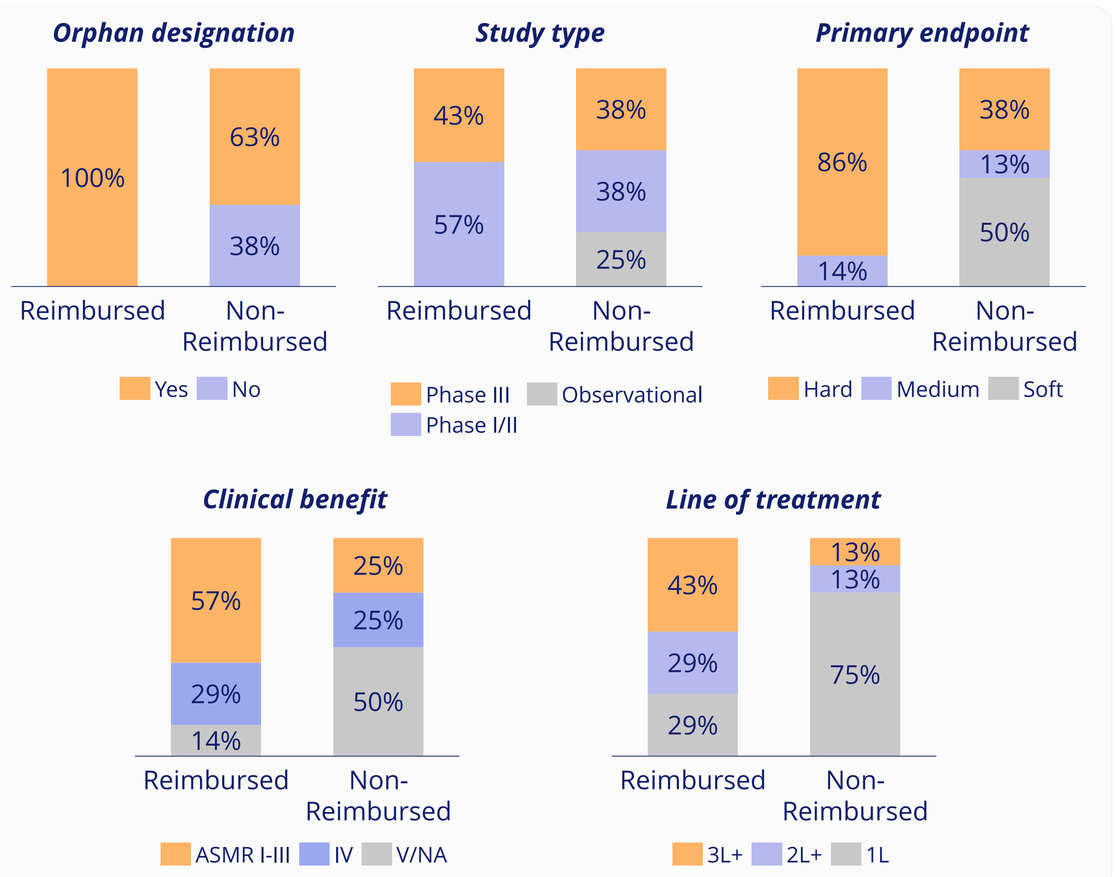
b) All reimbursed therapies were **approved based on phase I-III clinical studies**, versus 75% of the non-reimbursed therapies

c) Notably, 86% of reimbursed therapies were studied using a **robust clinical variable** as a primary endpoint versus 38%

d) In terms of clinical benefit, 57% of reimbursed ATMPs ***demonstrated a clear clinical advantage*** (ASMR level in France) versus 25%

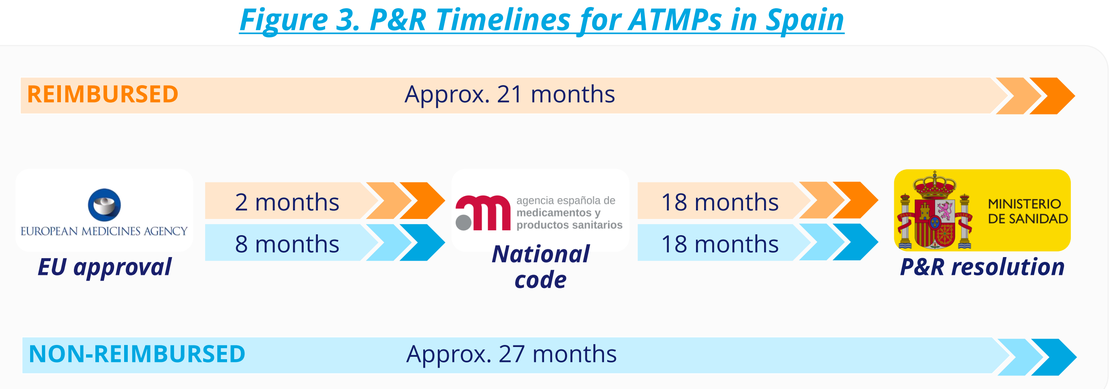
e) 43% were treatments for **third-line or later** (3L+), suggesting a focus on patients with advanced diseases versus 13%

Figure 2. Comparisons between Reimbursed (n=7) and Non-Reimbursed ATMPs (n=8)



> The average **time from European approval to P&R resolution** was 21 months for reimbursed therapies, compared to 27 months for non-reimbursed therapies (Figure 3 [1,3])

Figure 3. P&R Timelines for ATMPs in Spain



CONCLUSION

> This analysis highlights the importance of making innovative therapies accessible while upholding stringent standards for clinical evidence and cost-effectiveness. The findings indicate that improving the efficiency of the approval process and implementing flexible reimbursement models could enhance patient access to advanced therapies in Spain

REFERENCES

1. European Medicines Agency (EMA) webpage; 2. Spanish Agency for Medicines and Health Products (*Agencia Española de Medicamentos y Productos Sanitarios,* AEMPS); 3. Alira Health analysis; 4. General Council of Pharmaceutical Colleges of Spain – Botplus webpage; 5. Ministry of Health – Nomenclator webpage; 6. Ministry of Health – Bifimed webpage

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