TRENDS IN REIMBURSEMENT AGREEMENTS FOR INNOVATIVE, ORPHAN, AND ONCOLOGICAL MEDICINES IN SPAIN (2020-2025)

PT33

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INTRODUCTION AND OBJECTIVE

- Ensuring affordable access to novel medicines has been identified as a policy priority among the Organization for Economic Co-operation and Development and European Union countries[1].
- Innovative medicines, along with orphan and oncological therapies, represent significant progress in addressing unmet medical needs. However, their high cost has led to the widespread adoption of financial and prescription control mechanisms, reflecting the need to balance innovation with sustainability.
- This analysis aims to understand the trends in price and reimbursement (P&R) for innovative, orphan, and oncological drugs in Spain from January 2020 to June 2025.

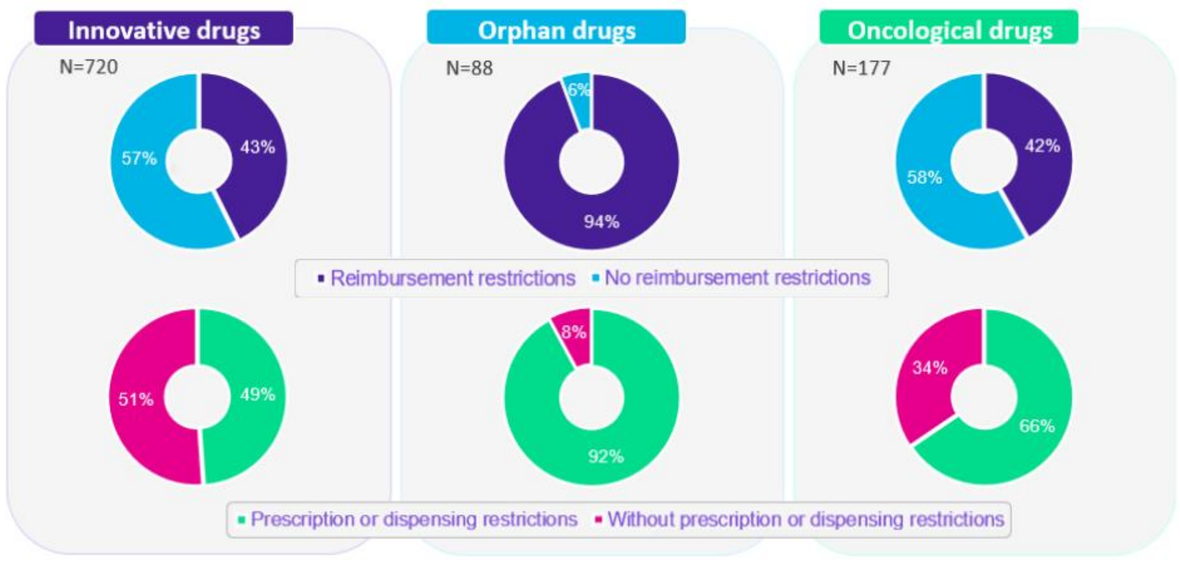
METHODS

- Data were extracted from BIFIMED[a], a public database on the reimbursement status and conditions of medicines managed by the Spanish Ministry of Health[2].
- The analysis focused on the different types of P&R agreements, as well as prescription and dispensing conditions (e.g., hospital use or diagnosis).
- This analysis focuses solely on new drugs or new indications for innovative drugs (defined as non-generic and/or non-biosimilar), orphan drugs, and oncological drugs (defined as ATC code L01). These categories were not mutually exclusive, and some drugs may overlap across groups.

RESULTS

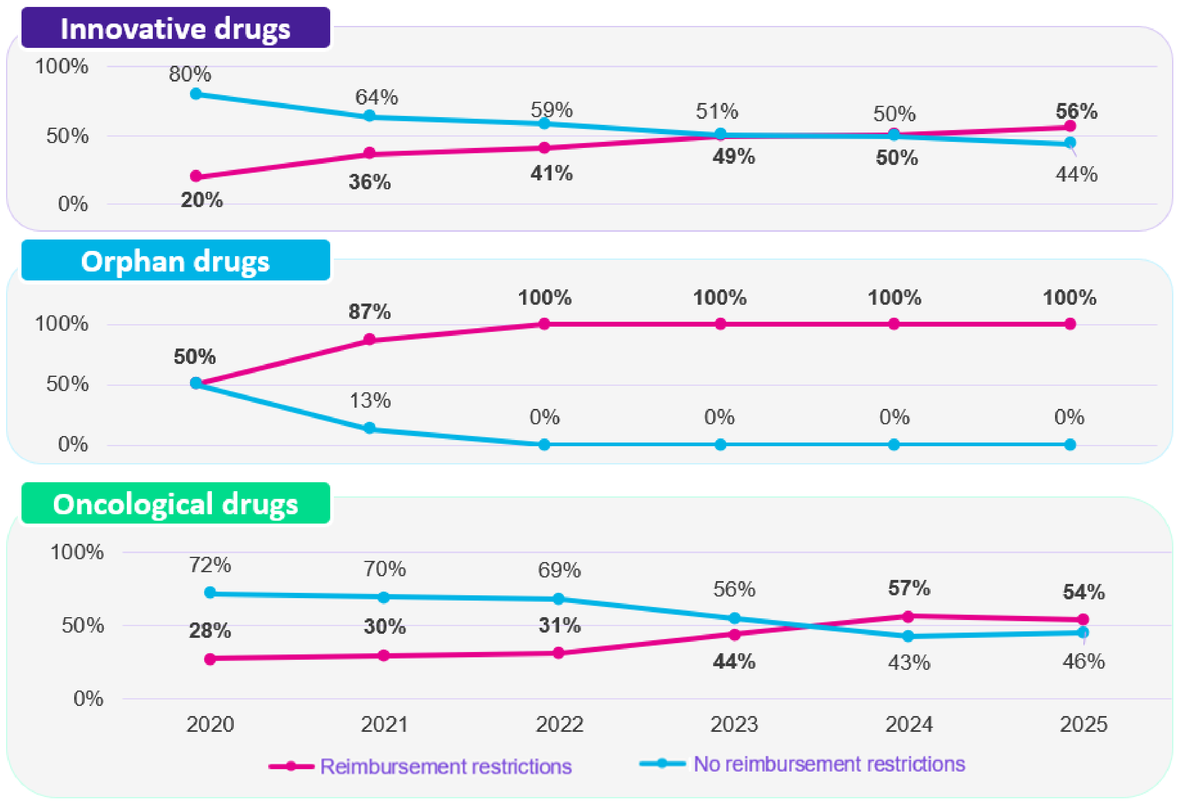
- Between 2020 and 2025, **43%** (n=307) **of innovative** drugs, **94%** (n=83) **of orphan** drugs and **42%** (n=74) **of oncological** drugs were subject to **limited P&R conditions through specific agreements** (Figure 1).
- **Restrictions on prescription or dispensing** were observed for **49% of innovative** drugs, **92% of orphan** drugs, and **66% of oncological** drugs (Figure 1).

Figure 1. Restrictions on reimbursement, prescription and dispensing



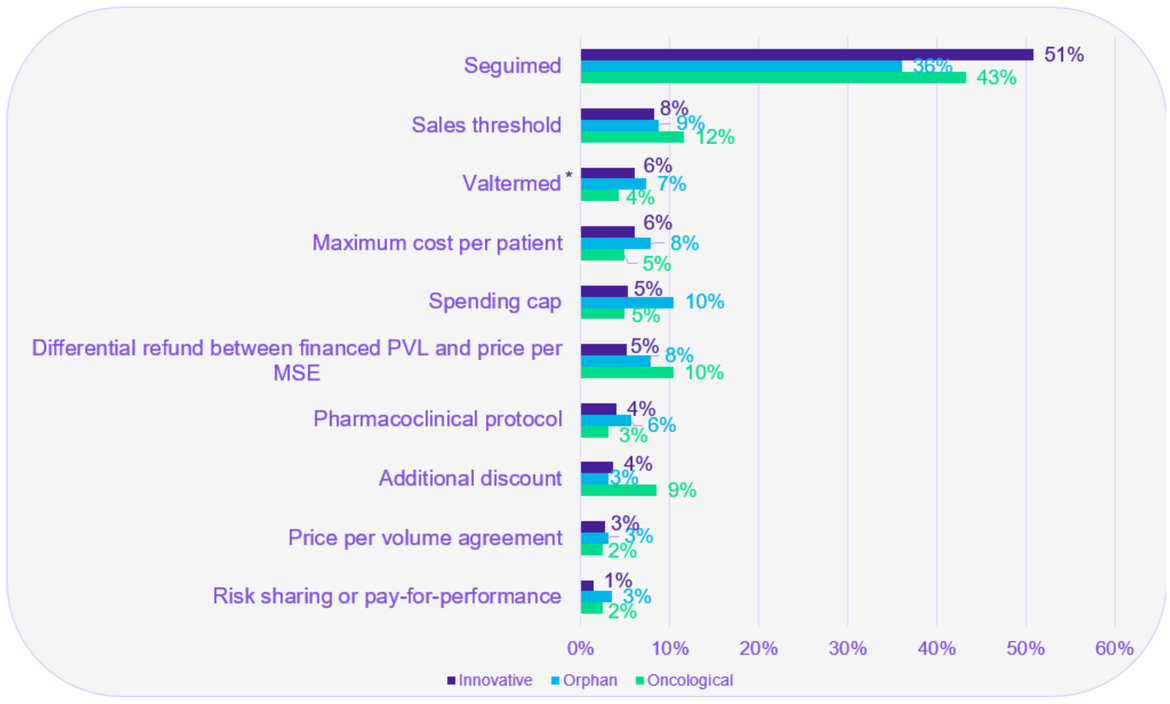
- Over the years, there has been a **clear trend towards more restrictions on P&R decisions.** For innovative drugs, the proportion subject to restrictions rose from 20% in 2020 to 56% in 2025. A similar trend was observed for oncological drugs, rising from 28% in 2020 to 54% in 2025. **Among orphan drugs, the trend was even more pronounced**, rising from 50% in 2020 to 100% in 2025 (Figure 2).

Figure 2. Evolution on reimbursement restrictions from 2020 to 2025



- **Seguimed[b] was the most common agreement** across all drug types (51% for innovative drugs, 36% for orphan drugs and 43% for oncological drugs) (Figure 3).
- **Spending cap and sales thresholds** were the agreements most applied for **orphan drugs**, besides Seguimed[b] (Figure 3).
- **Oncological drugs were more often subject to sales thresholds and payback mechanisms** (i.e., the difference between the ex-factory reimbursed price and the foreign price used for drugs in special situations) (Figure 3).

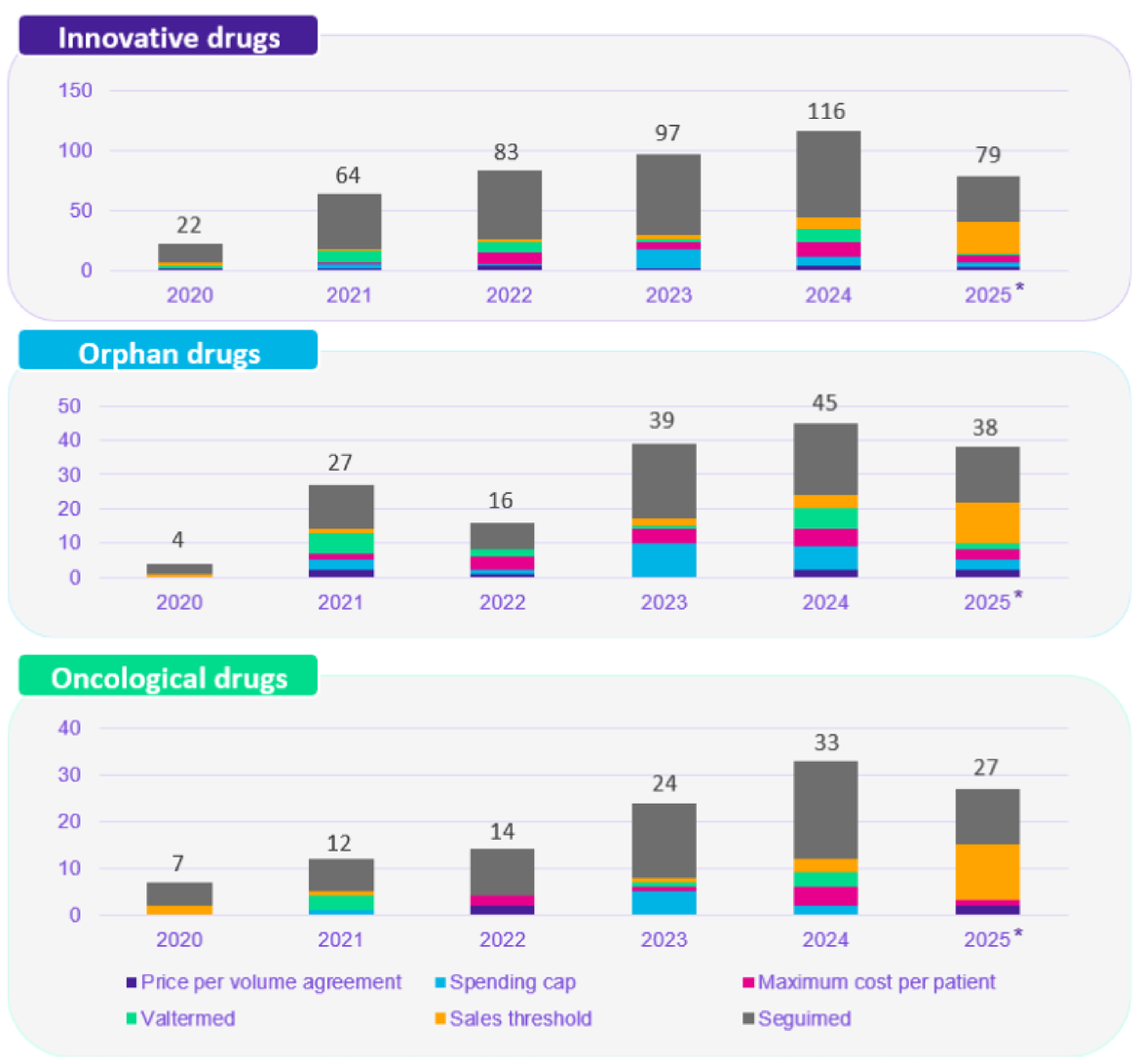
Figure 3. Type of P&R agreements from 2020 to 2025



Abbreviations: PVL, ex-factory price; MSE: medicines in special situations. Note: Only agreements with a frequency ≥2% have been included. *System designed to assess the therapeutic value of high-impact medicines in real-world clinical practice within the National Health System.

- Among drugs with restrictions on reimbursement, all the drug categories show a **steady rise in the number of restriction agreements from 2020 to 2024**, peaking in 2024. The decrease in 2025 may be due to the analysis ending in June of that year, meaning that only partial data for that year is included (Figure 4).
- These agreements **increasingly incorporated monitoring and financial control mechanisms** (Figure 4).

Figure 4. Evolution of the most frequent P&R agreements



*The analysis included data up to June 2025, meaning that, in 2025, the dataset covered only the first six months of the year compared to full-year data available for previous years.

CONCLUSIONS

- **These findings suggest an alignment between drug categories and the characteristics of the agreements applied to them.**
- **The widespread use of Seguimed[b] underscores the importance of monitoring systems within managed entry agreements.**
- **The frequent use of financial agreements for orphan drugs mainly reflects efforts to address high treatment costs, while the use for oncological drugs suggests a focus on controlling expenditure driven by high treatment volumes.**

NOTES AND REFERENCES:

[a] BIFIMED: Search engine for information on the financing situation of medicines; [b] Seguimed: System for tracking and monitoring the prescription and dispensing of medicines, ensuring compliance with established protocols.

1. Chapman SA, et al. Exploring the feasibility of monitoring access to novel medicines: A pilot study in EU Member States. OECD Health Working Papers. 2023:151. Available at: https://www.oecd.org/en/publications/exploring-the-feasibility-of-monitoring-access-to-novel-medicines_8c1d16c4-en.html; 2. Ministerio de Sanidad. BIFIMED: Buscador de la Información sobre la situación de financiación de los medicamentos - Nomenclátor de OCTUBRE - 2025. Available at: https://www.sanidad.gob.es/profesionales/medicamentos.do