Evolution of Pharmaceutical Pricing and Reimbursement Agreements in Spain Over the Last 10 Years: Towards an Outcomes-Based Approach

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Background

Pharmaceutical reimbursement is key to ensuring timely patient access and health system sustainability. The rise of therapeutic innovation, market competition, and per- sonalized medicine has intensified pressure on healthcare systems, highlighting the need to reassess reimburse- ment models to ensure resource efficiency and equitable access.[1-2]

Objectives

To analyze the evolution of pharmaceutical pricing and public reimbursement decisions in Spain over the past decade (2015-2024).

Methods

Data were extracted from the Spanish Ministry of Health's BIFIMED database[3], including all medicines reimbursed between January 2015 and December 2024. Each record included variables related to:

- Identification and formulation (e.g., active ingredient, trade name, formulation)
- Regulatory and reimbursement status (e.g., financing situation, price agreements, reference groups)
- Manufacturer information (e.g., marketing authorization holder, centralized procedure).

All variables were cleaned and standardized using Microsoft Excel, and an interactive Power BI dashboard was developed to visualize the characteristics and temporal trends of reimbursed medicines.

Within this dataset, medicines subject to Special Funding Conditions (SFC) were further classified into five predefined categories:

- **MEA** – Managed Entry Agreements: Financial schemes (discounts, rebates, caps) linked to sales, patients, or dosing thresholds; easy to implement via billing data.
- **ZCA** – Zero Cost Agreements: The manufacturer covers initial units/tests; the payer assumes costs only if the patient responds.
- **RSA** – Risk-Sharing Agreements: Payment contingent upon clinical outcomes or biomarkers; require robust data collection systems.
- **PRM** – Patient Registry & Monitoring: Enable RSAs and ZCAs (e.g., VALTERMED for outcomes and SEGUIMED for supply tracking).
- **REAM** – Regulatory & Exceptional Access Mechanisms: Define target population, dosage, and care pathways; shape funding conditions.

Results

From over 51,000 medicines identified in the database, 8,588 were reimbursed during the study period. The analysis focused on 1,353 innovative medicines (15.8%), excluding generics, biosimilars, and duplicate presentations (Figure 1).

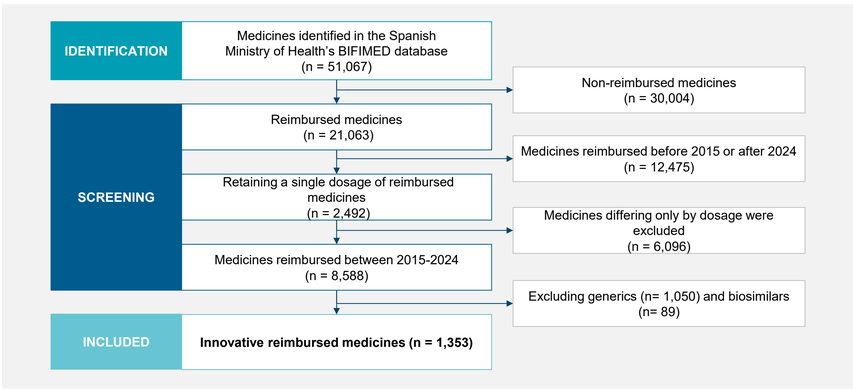

Figure 1. Selection of reimbursed medicines included in the analysis (2015–2024)

- Among innovative medicines 215 (15.9%) were biologics (Table 1 and Figure 2).
- Regarding dispensing channels, 569 medicines (42.1%) were designated for hospital dispensing and 784 (57.9%) for community pharmacy dispensing (Figure 3).
- Overall, hospital dispensing showed a modest upward trend, rising from approximately 40% in 2015 to 50–60% in 2024. This indicates a greater workload for hospitals and their pharmacy departments, due to both medicine dispensing and the data collection required for PRM agreements (Figure 2).
- Orphan drugs accounted for 6.5% (n=88), rising notably from 1 orphan drug reimbursed in 2015 to 19 in 2024, with 97.7% assigned to hospital dispensing (Figure 4 and Figure 5).
- Since 2020, reimbursement decisions involving special financing mechanisms (particularly PRM and MEA) have risen sharply, representing approximately 70% of all decisions in 2023 (Figure 2).

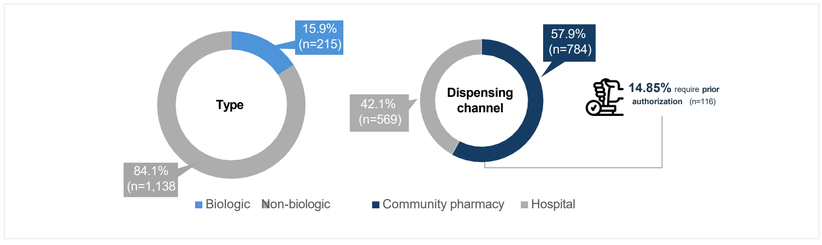

Figure 3. Innovative reimbursed medicines

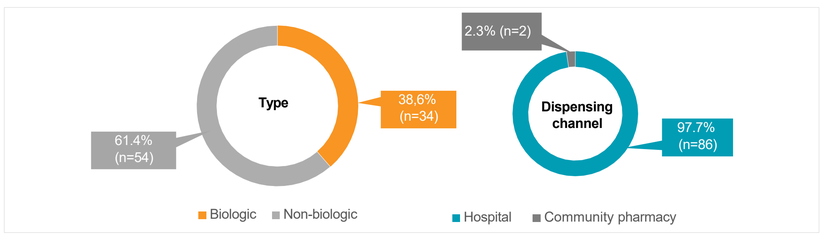

Figure 4. Orphan medicines (6.5%; n=88)

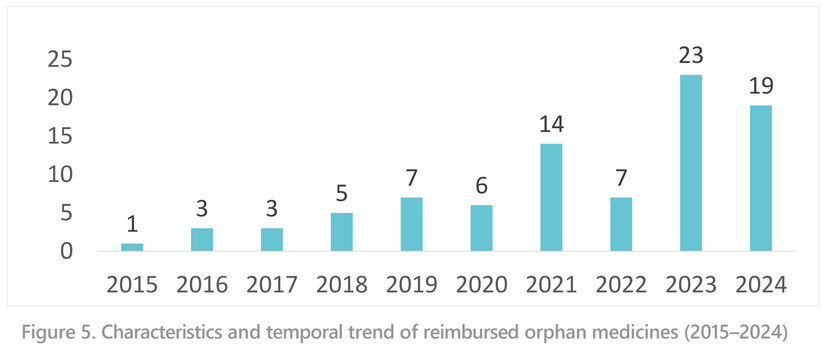

Figure 5. Characteristics and temporal trend of reimbursed orphan medicines (2015–2024)

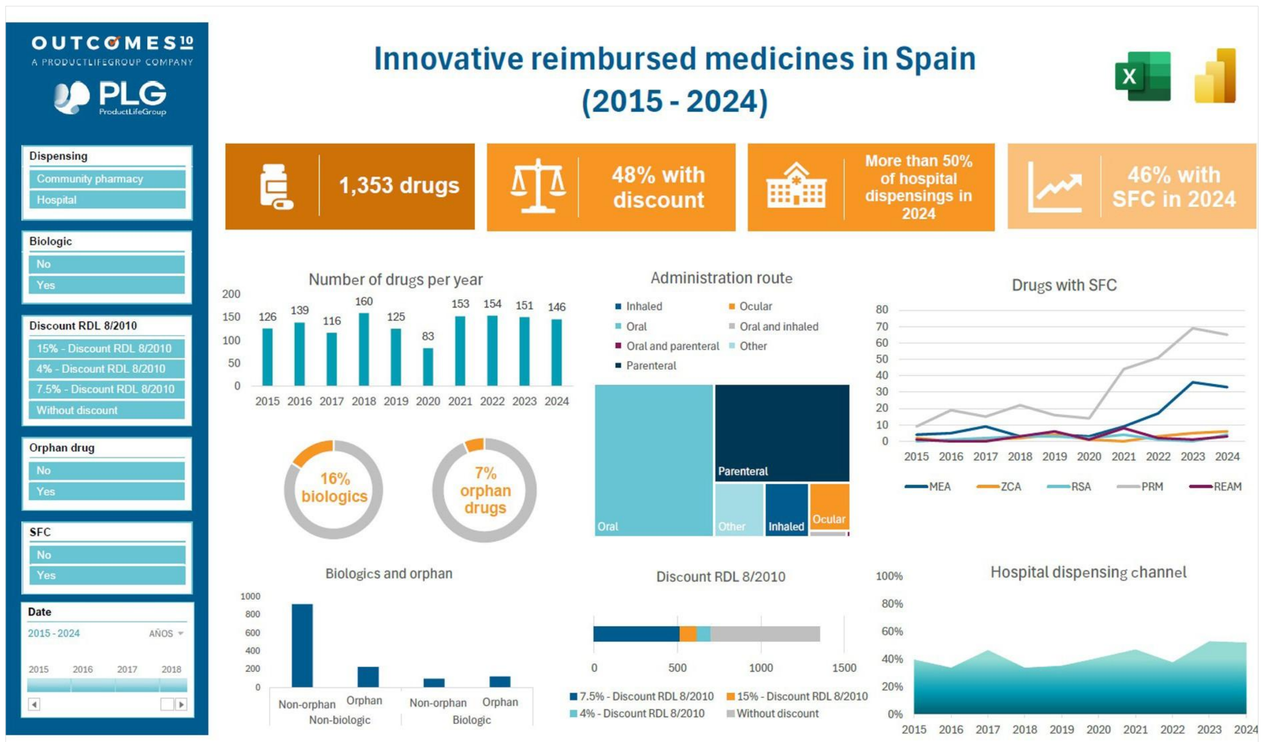

Figure 2. Dashboard summarizing key characteristics and trends of innovative reimbursed medicines in Spain (2015–2024)

	Innovative reimbursed medicines (n = 1,353)
Biologic	**215 (15.89%)**
Orphan condition	**88 (6.50%)**
Administration route	
Oral	*634 (46.86%)*
Inhaled	*83 (6.13%)*
Ocular	*68 (5.03%)*
Parenteral	*463 (34.22%)*
Oral and inhaled	*9 (0.67%)*
Oral and parenteral	*1 (0.07%)*
Other	*95 (7.02%)*
Hospital use	**387 (28.60%)**
Hospital diagnosis	**204 (15.08%)**
Centralized procedure	**524 (38.73%)**
Prescription required	**1348 (99.63%)**
Requires prior authorization (visado)	**116 (8.57%)**
Without price seal (SCP)	**182 (13.45%)**
Hospital dispensing	**569 (42.05%)**
User co-payment	
Exempt	*607 (44.86%)*
Standard	*429 (31.71%)*
Special	*317 (23.43%)*
RDL 8/2010 discount	
Without discount	*652 (48.19%)*
With discount (4%/7.5%/10%)	*701 (51.82%)*
SFC	**345 (25.50%)**
MEA	*123 (9.09%)*
ZCA	*24 (1.77%)*
RSA	*20 (1.48%)*
PRM	*324 (23.95%)*
REAM	*25 (1.85%)*

MEA, Managed Entry Agreements; PRM, Patient Registry and Monitoring systems; REAM, Regulatory and Exceptional Access Mechanis ms; RDL, Royal Decree-Law; RSA, Risk-Sharing Agreements; SCP, Without price seal (sin cupón precinto); SFC, Special Funding Condition; ZCA, Zero Cost Agreements.

Table 1. Characteristics of the 1,353 innovative reimbursed medicines included in the analysis

Conclusion

Over the past decade, Spain has reinforced access to innovative treatments, including a growing number of biologics and orphan drugs, many dispensed at hospitals. The increase in SFCs indicates a shift toward enhanced financial oversight and clinical accountability.

Generating robust evidence to demonstrate clinical value, predict economic impact through advanced modelling techniques and pharmacoeconomic analysis, and confirm real-world outcomes will be essential to sustain access to therapies subject to complex reimbursement process.

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