

ACCESS TO ORPHAN DRUGS IN SPAIN COMPARED WITH EU-4 COUNTRIES: REIMBURSEMENT DIFFERENCES AND LACK OF TRANSPARENCY ACROSS EUROPE

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BACKGROUND & OBJECTIVES

Access and reimbursement of orphan drugs (ODs) varies among EU-5 countries [1]. Pricing and Reimbursement (P&R) decisions are made at national level, using different evidence requirements, reimbursement criteria, reimbursement timelines, and different OD prices between countries [1,2]. The aim of this work is to assess the current P&R situation of ODs approved in Spain between 2012 & 2016, comparing the reimbursement status of ODs with France, Germany, Italy and the United Kingdom (UK) (EU4).

METHODS

ODs approved by the European Commission (EC) between 2012-2016 and with a request for authorisation in Spain were included in the study and classified into three P&R categories: approved, undergoing decision and rejected. Results were compared to ODs' reimbursement status and price, in case they were reimbursed, in EU4 countries.

Table 1: ODs databases used to understand reimbursement status and price in EU-5*

EU-5 Country	Reimbursement status	ODs price
Germany	LauerTaxe database [3]	LauerTaxe database
Italy	CODIFA database [4]	CODIFA database
Spain	No direct information of reimbursement status is available. Several sources were searched: The Spanish Online Medicines Information Centre (CIMA) [5], Spanish Medicine Agency (AEMPS) webpage [6] and the Spanish Ministry of Health webpage [7].	Botplus database [8]
UK	NICE webpage [10] & list of medicines commissioned by NHS [11]	MIMS database [12]
France	AMELI database [13] & Ministry of Social Affairs and Health webpage [14]	AMELI database

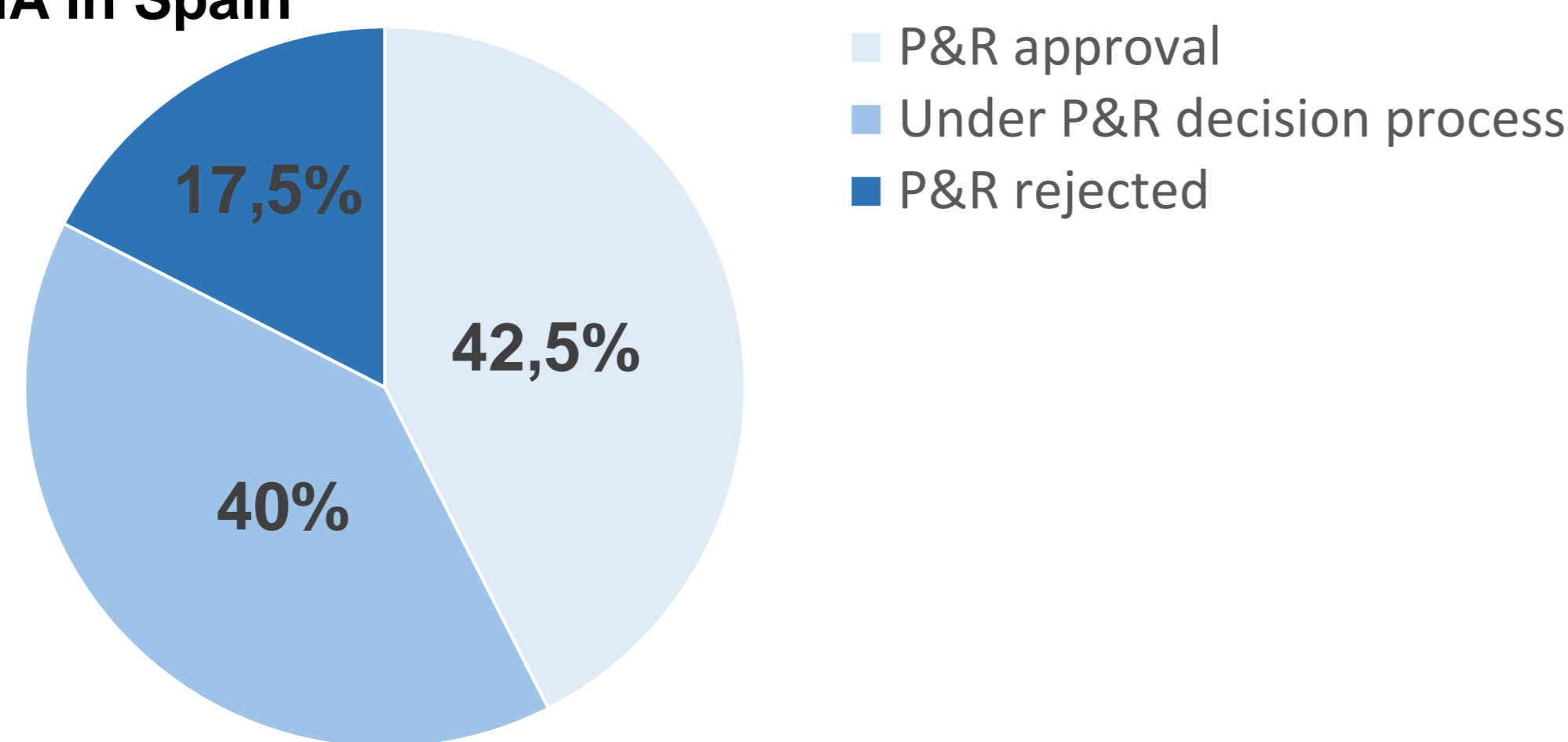
*Databases were accessed between January and March 2017.

RESULTS

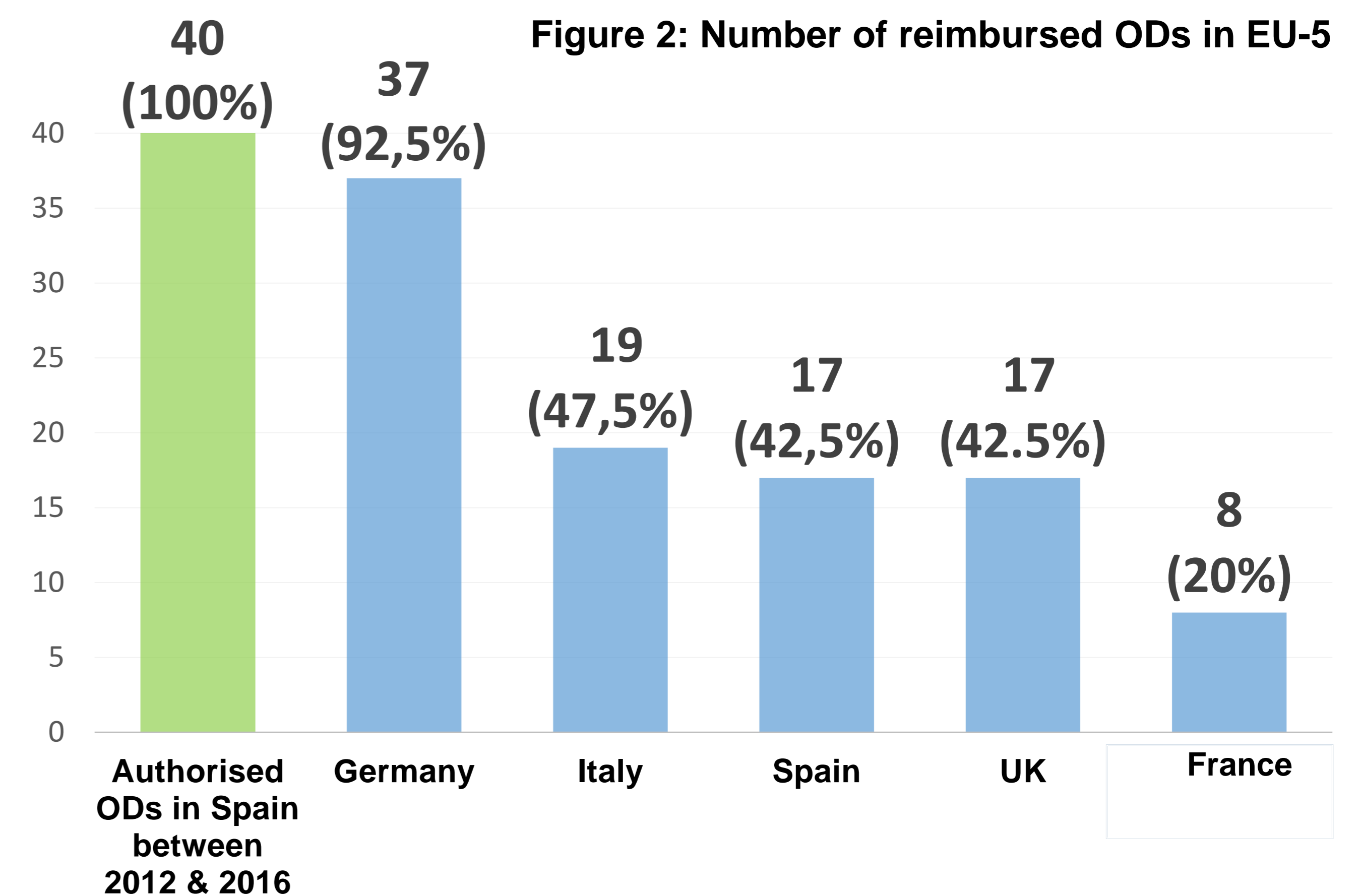
ODs reimbursement in Spain

- A total of 57 ODs were approved by the European Commission (EC) between 2012 & 2016, from which 40 ODs were identified as having marketing authorisation (MA) in Spain.
- From the 40 identified ODs, 17 (42.5%) had P&R approval, 16 (40%) were undergoing P&R decision process and 7 (17.5%) had their P&R requests rejected in Spain.

Figure 1. P&R status of EC approved ODs between 2012-2016 with MA in Spain



ODs reimbursement in EU5 countries



Price of ODs in EU-5 countries

Table 2: List price of ODs with P&R approved in Spain in EU-5 countries and price differential vs. Spanish price

OD	Date of EC approval	Spanish price	UK price	Price Differential vs Spanish price (Δ)	Italian price	Price Differential vs Spanish price (Δ)	French price	Price Differential vs Spanish price (Δ)	German price	Price Differential vs Spanish price (Δ)
Darzalex®	20/05/2016	€ 2,380.73	€ 1,688.67	-29.07%	-	-	-	-	€ 2,324	-2.38%
Cresemba®	15/10/2015	€ 700	-	-	€ 631.75	-9.75%	-	-	€ 748.70	+6.96%
Kyprolis®	19/11/2015	€ 1,339	€ 1,238.36	-7.52%	€ 1,147.17	-14.33%	-	-	€ 1,236.95	-7.72%
Lenvima®	28/05/2015	€ 1,874.87	€ 1,685.16	-10.12%	€ 1,692.07	-9.75%	€ 1,556.70	-16.97%	€ 1,798.50	-4.07%
Ofev®	15/01/2015	€ 2,403.85	€ 2,522.57	+4.94%	€ 2,454.16	+2.09%	€ 2,060.40	-14.29%	€ 2,428.77	+1.04%
Adempas®	27/03/2014	€ 1,260	€ 1,169.59	-7.18%	€ 1,259.73	-0.02%	-	-	€ 1,021.10	-18.96%
Gazyvaro®	23/07/2014	€ 3,970	€ 3,883.95	-2.17%	-	-	-	-	€ 3,252.56	-18.07%
Imbruvica®	21/10/2014	€ 8,777.50	€ 7,190.94	-18.08%	€ 8,088.20	-7.85%	-	-	€ 7,296.10	-16.88%
Lynparza®	16/12/2014	€ 4,980	€ 4,163.05	-16.40%	€ 4,882.13	-1.97%	-	-	€ 5,482.54	+10.09%
Sylvant®	22/05/2014	€ 536.46	€ 486.67	-9.28%	€ 455.76	-15.04%	-	-	€ 519.40	-3.18%
Imnovid®	05/08/2013	€ 9,300	€ 10,418.18	+12.02%	€ 8,885.11	-4.46%	-	-	€ 7,862.50	-15.46%
Opsumit®	20/12/2013	€ 2,450	€ 2,704.22	+10.38%	€ 2,572.13	+4.98%	-	-	€ 2,254	-8%
Orphacol®	12/09/2013	€ 8,731.75	€ 7,774.93	-10.96%	-	-	-	-	€ 11,152.27	+27.72%
Adcetris®	25/10/2012	€ 3,300	€ 2,931.73	-11.18%	€ 3,333	+1%	-	-	€ 3,188.50	-3.38%
Dacogen®	20/09/2012	€ 1,111.05	€ 1,138.52	+2.47%	€ 1,110.08	-0.09%	-	-	€ 1,214.16	+9.28%
Kalydeco®	23/07/2012	€ 18,000	€ 16,417.66	-8.79%	€ 17,999.85	0%	€ 18,000	0%	€ 17,400	-3.33%
Signifor®	24/04/2012	€ 2,617	€ 3,799.52	+49.15%	€ 4,123.34	+57.56%	€ 2,837.80	+8.44%	€ 2,846.17	+8.76%

The most expensive drug presentation is shown in the Table. Colour green is used to indicate a positive price differential, meaning that the price is higher compared to Spain. Colour red is used to indicate a negative price differential, meaning that the price is higher in Spain.

Drug prices in the EU5 countries were searched for each OD with P&R approval in Spain. According to existing price databases, results showed that **Spain is the country with the highest OD prices within the EU-5**, as 11 of the 17 analysed ODs (64.7%) had their highest official price in Spain. Prices in the table correspond to official listed prices, which do not reflect price negotiations that can lower the real, reimbursed price up to a 50% over the listed price, depending on the country [15,16].

CONCLUSIONS

Reimbursement of ODs varies within the EU-5 countries, being Germany the country with the most ODs reimbursed (37), followed by Italy (19), Spain & UK (17) and France (8). EU5 countries might have different value drivers to reimburse ODs, as no common criteria for reimbursement appear to exist. Spain seems to have the highest OD prices within the EU5. It is really difficult to understand how cost-effectiveness analyses using the list price to assess value of new drugs would be valid, as real, reimbursed prices can vary between 10%-50% from the list price in certain countries [15,16].

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