

REPORT ON ACCESS TO ORPHAN MEDICINAL PRODUCTS IN SPAIN

SECOND FOUR-MONTH PERIOD OF 2021



Status of access to orphan medicinal products (OMP) possessing a trade name and positive orphan designation in force as of the 31th of August, 2021

OMP IN THE EU AND SPAIN

173

Products possessing a trade name and positive orphan designation

126

OMP with community marketing authorisation

107

OMP with National Code in Spain (85%)

51

OMP funded by the Spanish National Health System (SNS) (40%)

SECOND FOUR-MONTH PERIOD OF 2021

9

New positive orphan designations in the EU

8

New community marketing authorisations

4

OMP have obtained a National Code in Spain

6

OMP have been funded by the SNS

OMP WITH FUNDING APPROVED IN SPAIN

% OF OMP FUNDED

43%

2019

40%

2020

39%

2021

40%

Second four-month period 2021

■ Annual average ■ Annual average ■ First four-month period Average

The % of OMP funded in Spain **increases by 1 point** compared to first four-month period 2021

AVERAGE FUNDING WAITING TIMES

Months between National Code and funding

13,9

2019

33,1

2020

27,8

2021

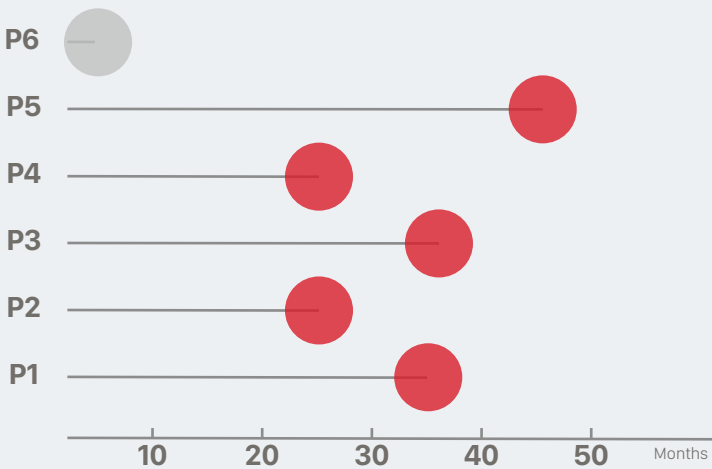
27,3

Second four-month period 2021

■ Annual average ■ Annual average ■ First four-month period Average

The average waiting time **decreases by 1.8% months point** compared to first four-month period 2021

Products



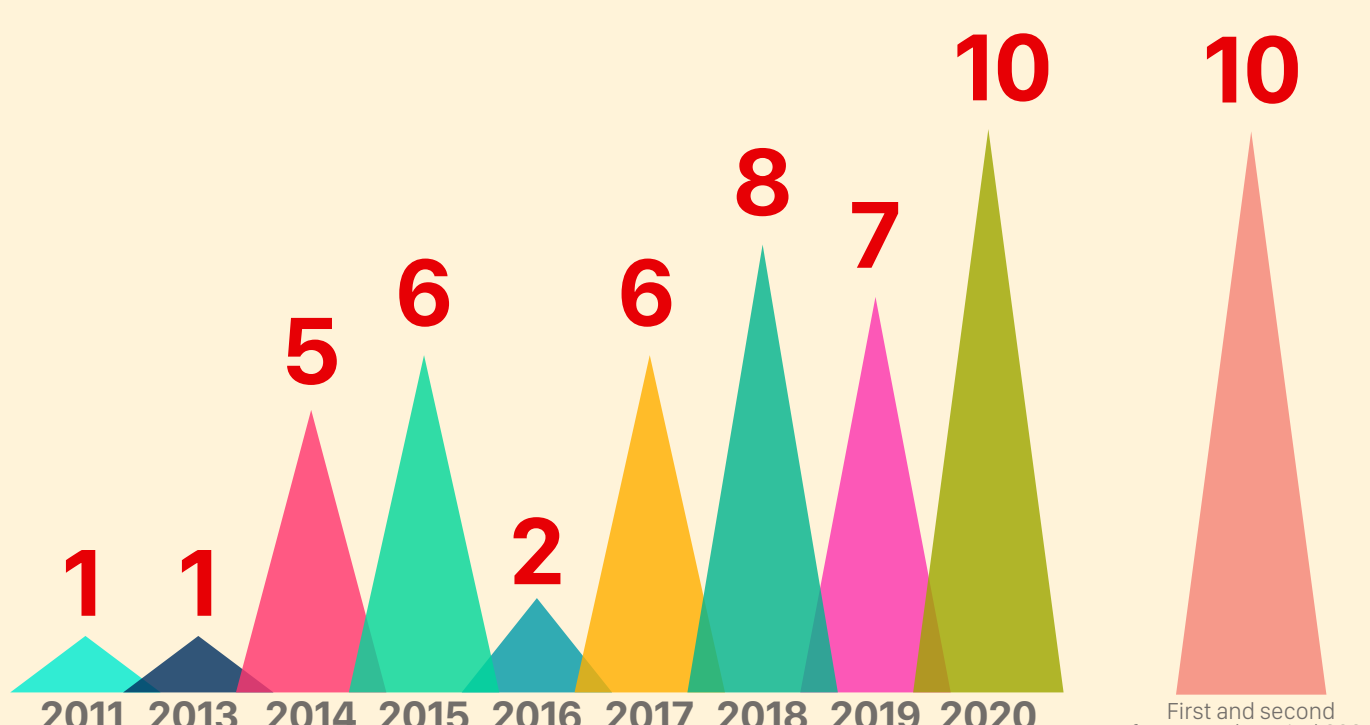
5 of the 6 OMP funded in the second four-month period had to wait **2 years or more** for decisions regarding pricing and reimbursement

OMP PENDING FUNDING IN SPAIN

Currently, **56 OMP** are still awaiting funding

NUMBER OF OMP PENDING FUNDING

2011 Y 2021



Report on access to orphan medicinal products in Spain



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*The sources used for the preparation of this report are always public and can be consulted at aelmhu.es