

ORPHAN DRUGS IN SPAIN REPORT ON ACCESS

FIRST FOUR-MONTH PERIOD 2022



Access status of Orphan Drugs (ODs) with trade names with orphan designation in force as of April, 30 of 2022

ODs IN UE AND SPAIN

181
Products with trade name and orphan designation

132
ODs with market authorization

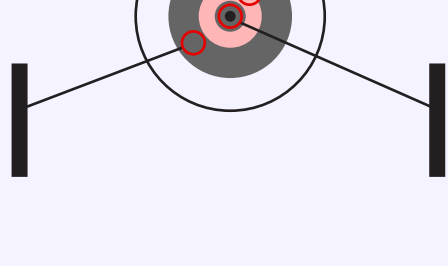
113
With National Code in Spain (86%)

58
Financed by the National Health System (44%)

FIRST FOUR-MONTH PERIOD 2022

8 New orphan designations in EU

6 New EMA market authorizations



4 ODs obtained the National Code in Spain

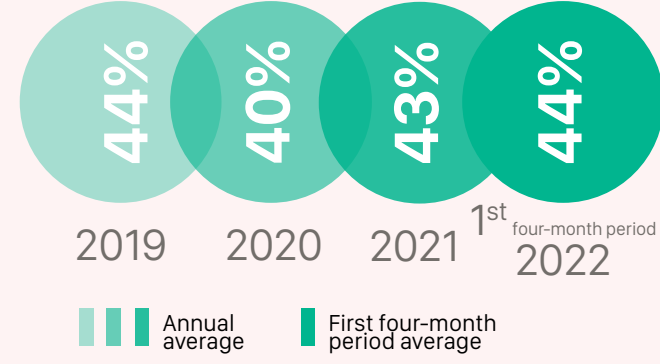
2 ODs financed by the National Health System

FINANCED ODs

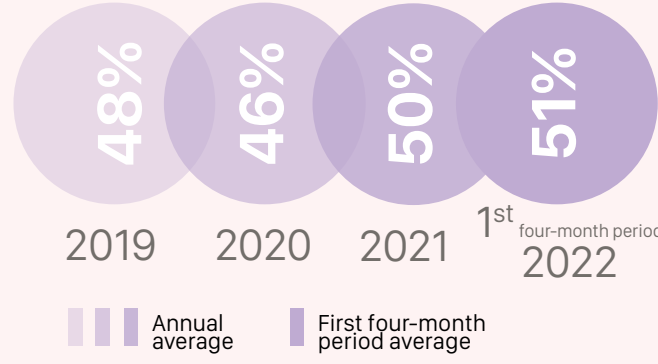
58 orphan drugs are financed by the National Health System

% FINANCED

ODs with market authorization and financed by the National Health System 2019 – 1st four-month period 2022

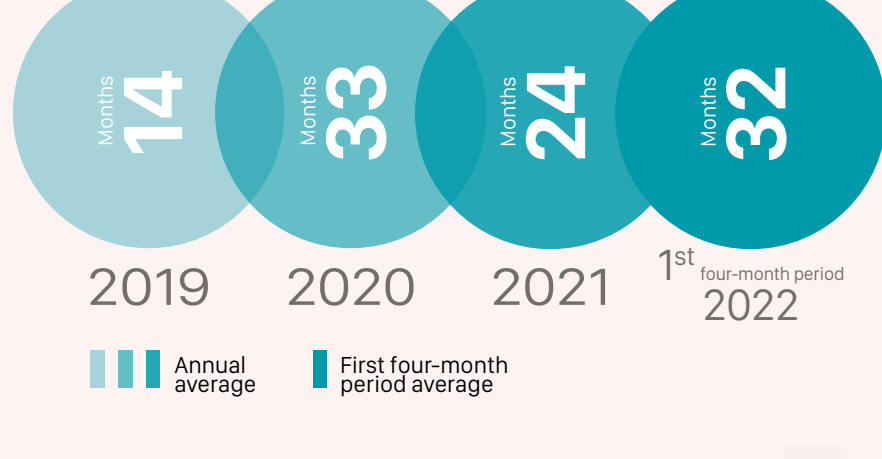


ODs with National Code and financed by the National Health System 2019 – 1st four-month period 2022



AVERAGE WAITING TIME

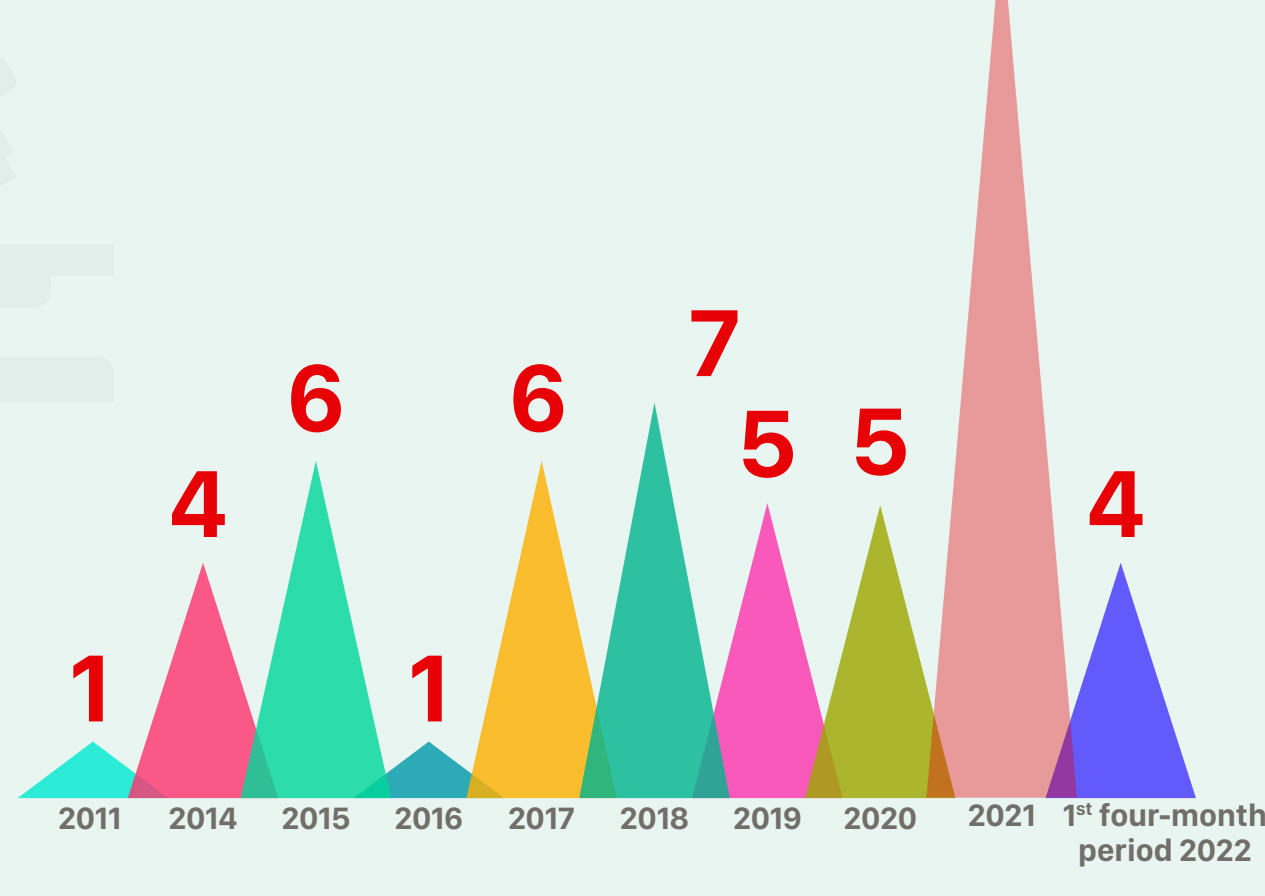
Months elapsed between National Code and entry into the National Health System



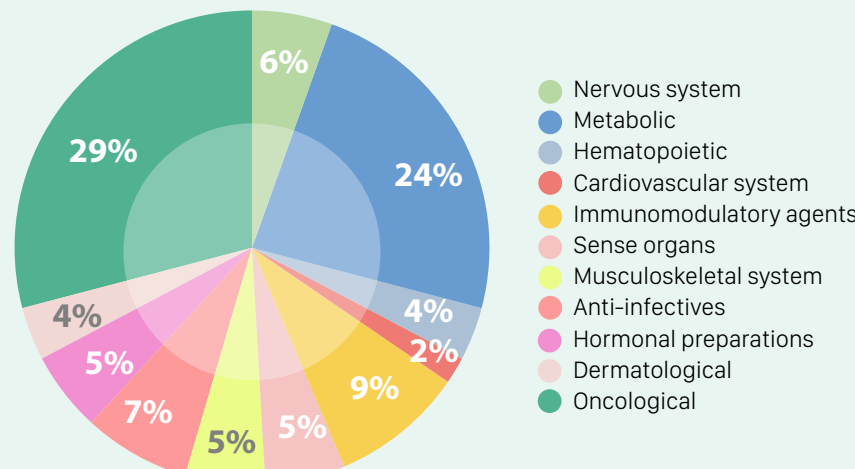
ODs UNFINANCED IN SPAIN

55 orphan drugs with National Code are waiting for a favorable price and financing resolution

NO. OF UNFINANCED ODs PER NATIONAL CODE YEAR



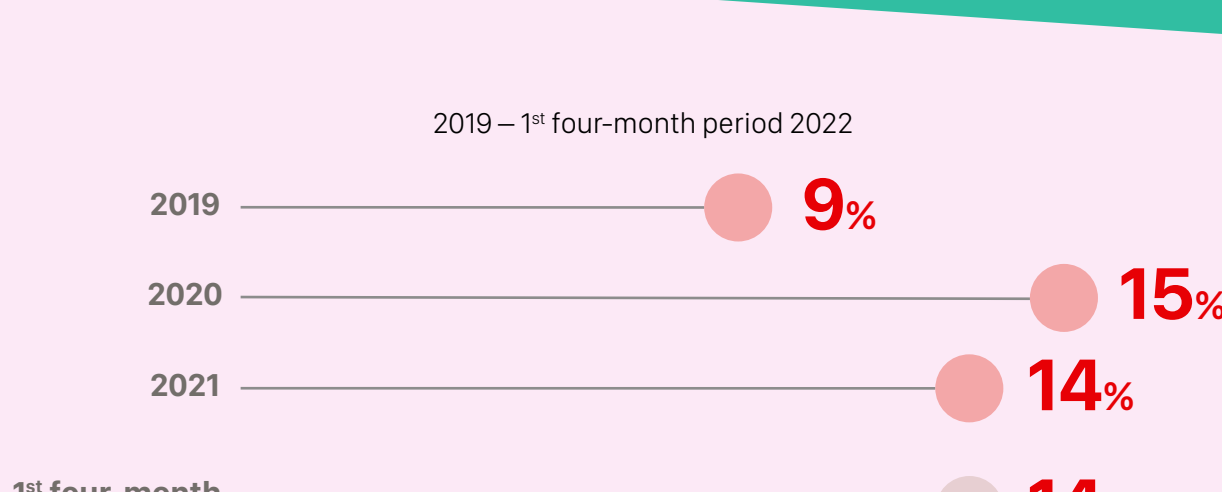
ODs UNFINANCED BY THERAPEUTIC AREA



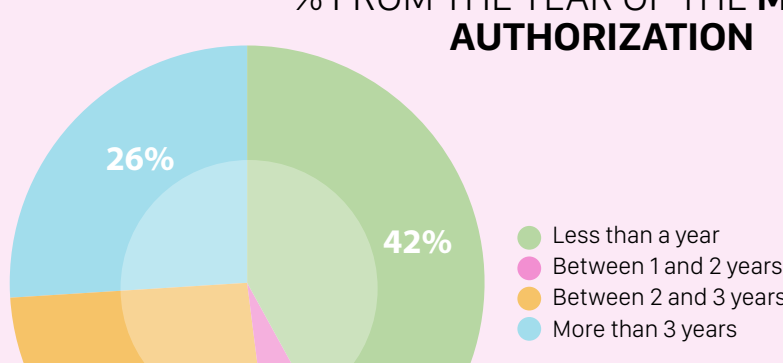
ODs WITH MARKET AUTHORIZATION WAITING FOR ARRIVAL TO SPAIN

19 DRUGS WITH MARKET AUTHORIZATION WITHOUT NATIONAL CODE

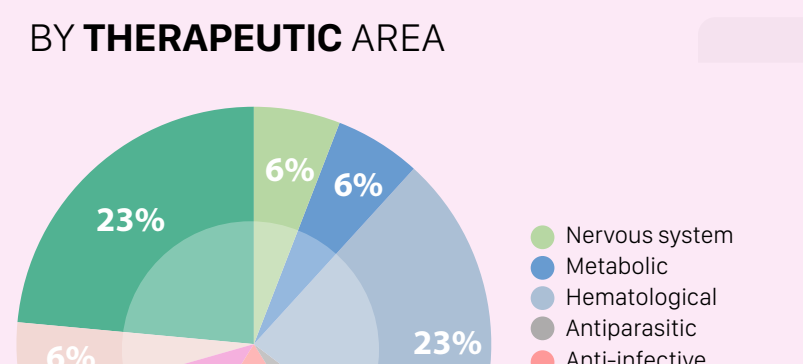
% ODs WITH MARKET AUTHORIZATION WITHOUT NATIONAL CODE



% FROM THE YEAR OF THE MARKET AUTHORIZATION



BY THERAPEUTIC AREA

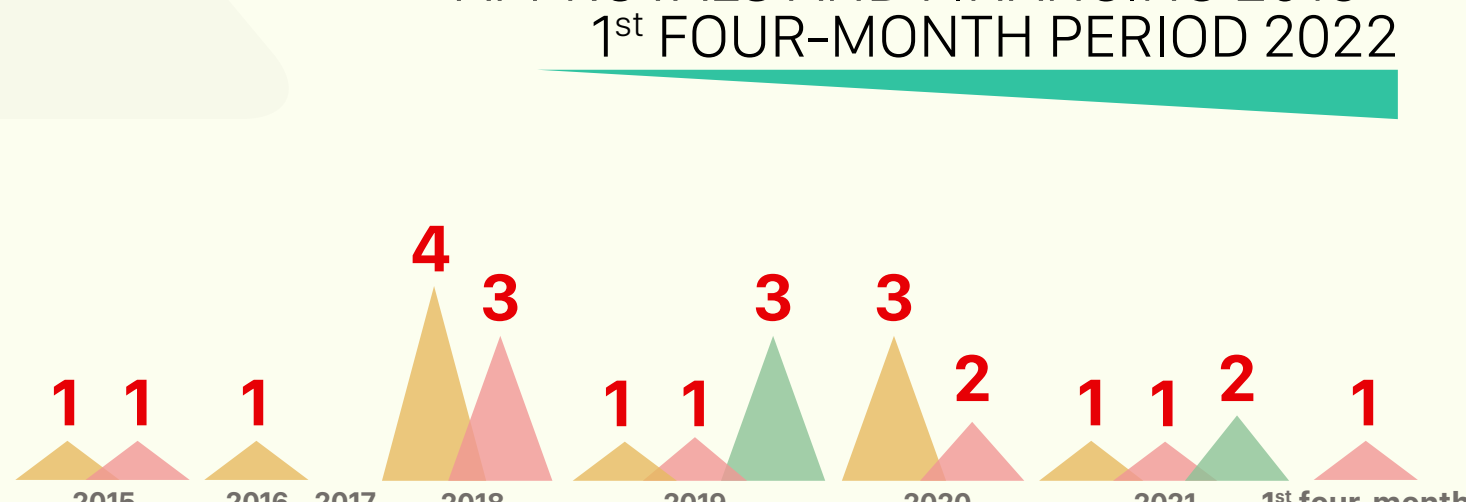


ADVANCED THERAPIES WITH ORPHAN DESIGNATION

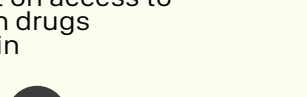
As of April 30, 2022 there are:

- 11 advanced therapies with market authorization in Europe
- 9 with National Code
- 5 financed by the National Health System

APPROVALS AND FINANCING 2015 - 1st FOUR-MONTH PERIOD 2022



Report on access to orphan drugs in Spain



The sources used in this report are Always public and can be consulted at aelmhu.es