

Access status of orphan drugs (ODs) with market name, with orphan designation in force as of August 31, 2022

ODs IN THE EU AND SPAIN

186

Products with trade name and orphan designation

137

ODs with market authorization (MA)

116

With National Code (NC) in Spain (85%)

59

Financed by the National Health System (43%)

SECOND FOUR-MONTH PERIOD 2022

11 New orphan designations in EU



6 ODs obtained National Code in Spain

9 New EMA market authorizations

4 ODs financed by the NHS

FINANCED ODs

59 Orphan drugs are currently financed by NHS

% FINANCED

ODs with market authorization and financed by NHS 2019 - 2022*



ODs with NC and financed by NHS 2019 - 2022*



47%
(28)

Financed with restrictions

(limitation of indications or unfunded indications)

AVERAGE WAITING TIME

Months elapsed between National Code and entry into the NHS



ODs UNFINANCED IN SPAIN

57 Orphan drugs with National Code not financed by the NHS

32 Not financed by resolution

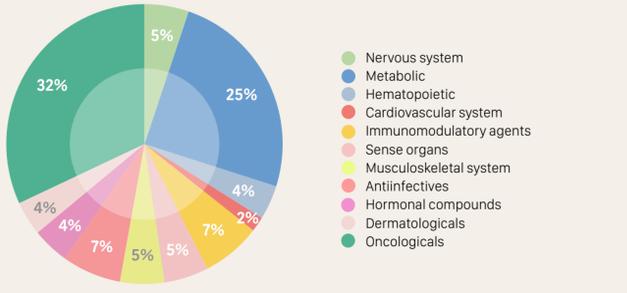
24 Under study or without funding request

1 Removal from the Nomenclature

NO. OF UNFINANCED ODs PER NATIONAL CODE YEAR



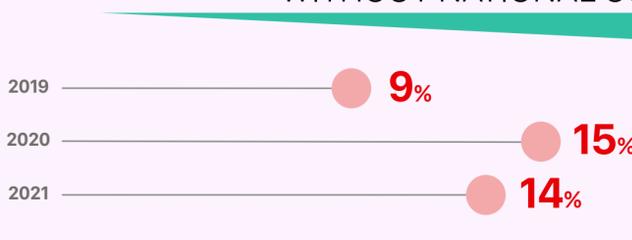
ODs UNFINANCED BY THERAPEUTIC AREA



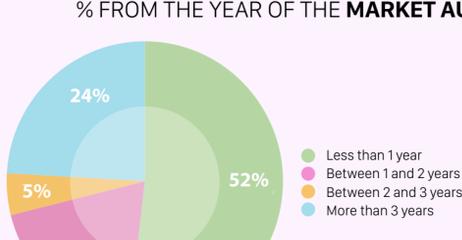
ODs WITH MARKET AUTHORIZATION WAITING FOR ARRIVAL TO SPAIN

21 DRUGS WITH MARKET AUTHORIZATION WITHOUT NATIONAL CODE

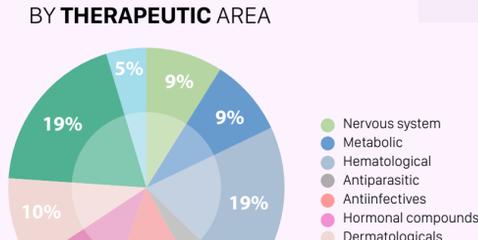
% ODs WITH MARKET AUTHORIZATION WITHOUT NATIONAL CODE



% FROM THE YEAR OF THE MARKET AUTHORIZATION



BY THERAPEUTIC AREA



ADVANCED THERAPIES WITH ORPHAN DESIGNATION

As of August 31, 2022 there are:

13 Advanced therapies with market authorization in Europe

10 With National Code

5 Financed by NHS

APPROVALS AND FINANCING 2015 - AUGUST 2022



*Cumulative data from January 1 to August 31, 2022.