

Access stats of Orphan Drugs (ODs) with trade name, with orphan designation in force as of 30 April 2023

ODs IN THE EU AND SPAIN

202

Products with trade name and orphan designation

146

ODs with EMA marketing authorisation (MA)

127

ODs With National Code (NC) in Spain (87%)

70

ODs Funded by the NHS (48%)

Jan-April 2023

9

New orphan designations in EU

5

ODs have obtained National Code in Spain

1

New EMA marketing authorisations

7

ODs have been funded by the NHS

ODs FUNDED IN SPAIN

70

Orphan drugs are currently funded by the NHS

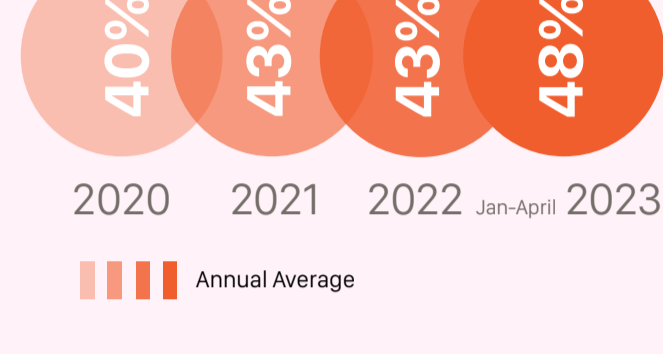
46%

(32)

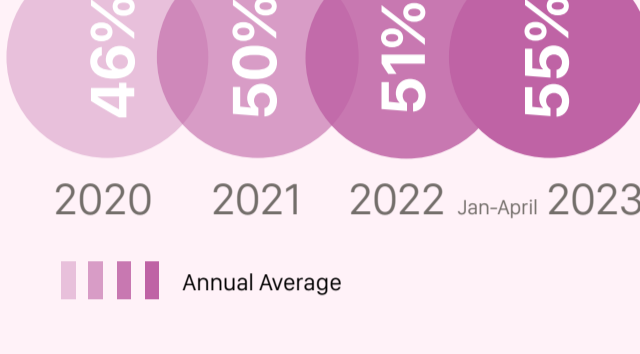
ODs restrictedly funded (limited or unfunded indications)

% FUNDED

ODs with marketing authorisation funded by the NHS 2020 – April 2023



ODs with NC funded by the NHS 2020 – April 2023



AVERAGE WAITING TIME

Months between NC and incorporation into the NHS



ODs NOT FUNDED IN SPAIN

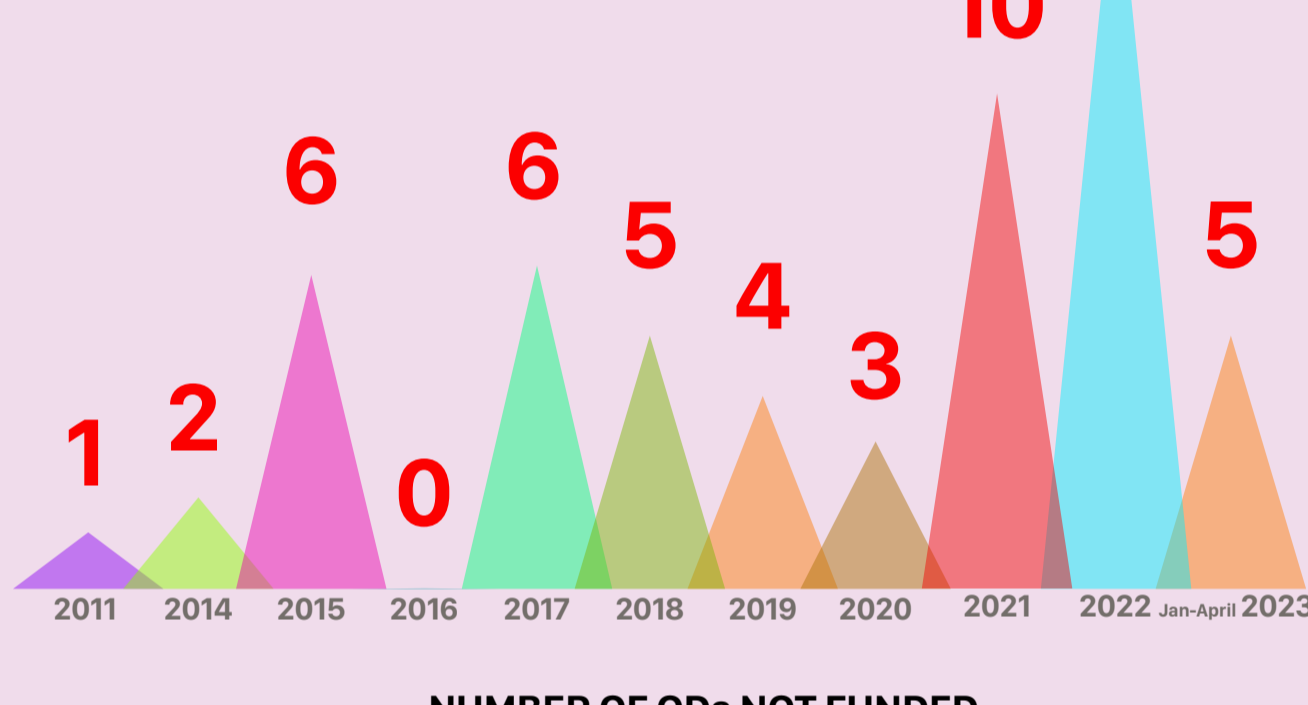
57

Orphan Drugs with NC not funded by the NHS

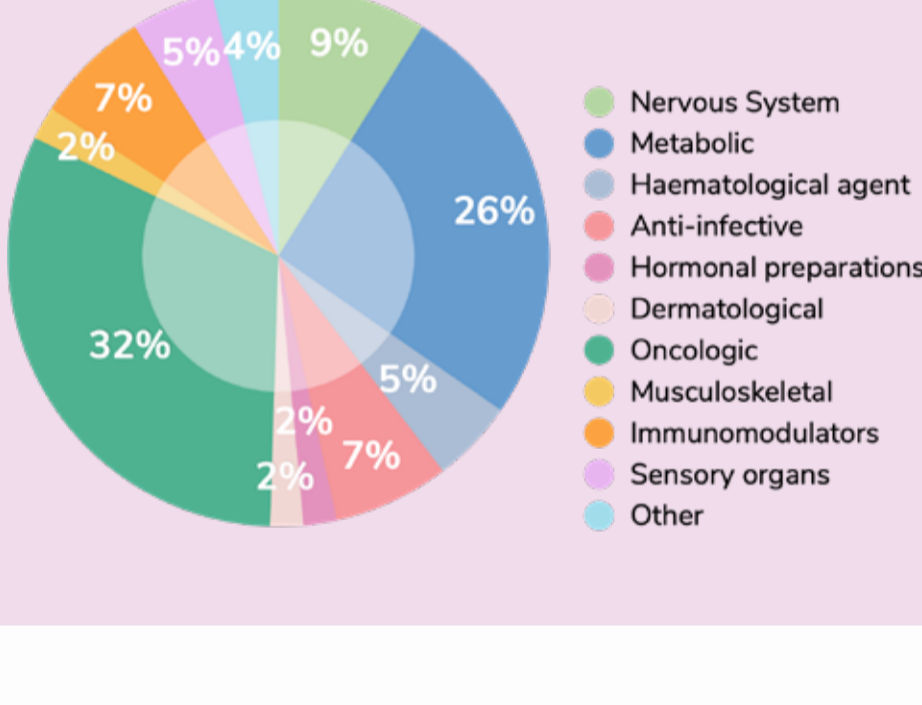
29 Not funded by resolution

28 Under study or without funding request

NUMBER OF ODs NOT FUNDED BY YEAR OF NC



NUMBER OF ODs NOT FUNDED BY THERAPEUTIC AREA



ODs WITH MA PENDING TO ARRIVE IN SPAIN

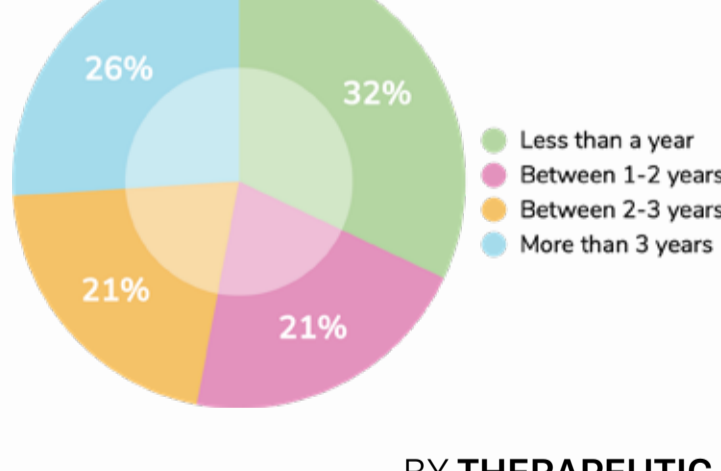
19

ODs WITH MA WITHOUT NC IN SPAIN

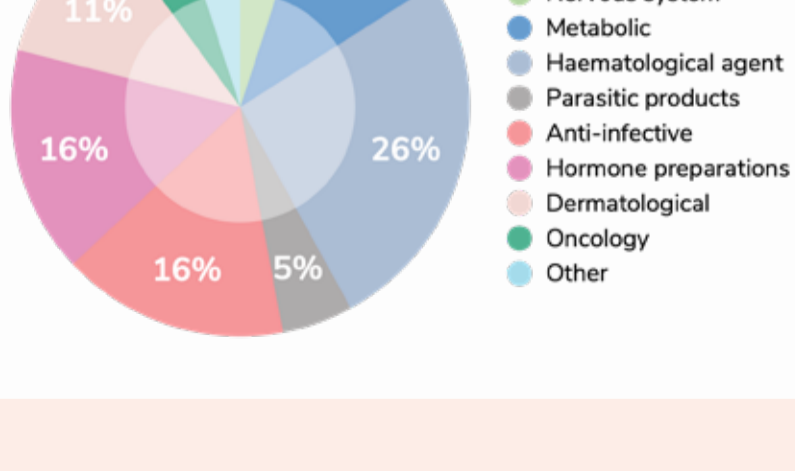
% ODs WITH MA WITHOUT NC



BY WAITING TIME SINCE MA



BY THERAPEUTIC AREA



ADVANCED THERAPIES WITH ORPHAN DESIGNATION

As of 30 April 2023 there are:

15

Advanced Therapies with MA in Europe

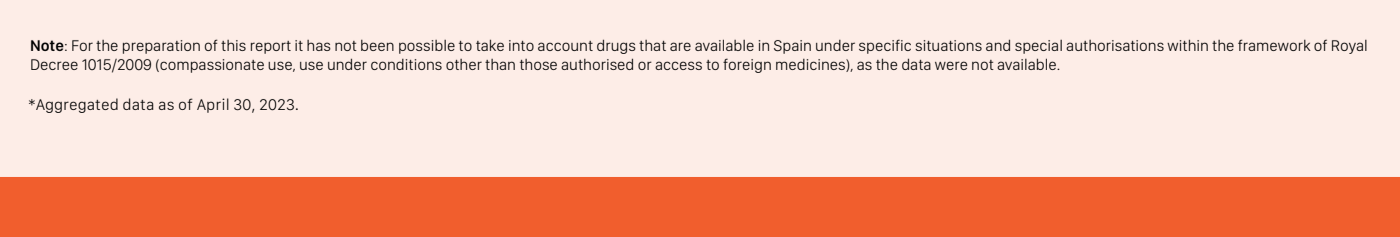
14

With NC

5

Funded by the NHS

APPROVALS AND FUNDING 2015



Note: For the preparation of this report it has not been possible to take into account drugs that are available in Spain under specific situations and special authorisations within the framework of Royal Decree 1015/2009 (compassionate use, use under conditions other than those authorised or access to foreign medicines), as the data were not available.

*Aggregated data as of April 30, 2023.