

ORPHAN DRUGS IN SPAIN
MARKET ACCESS REPORT
MAY-AUGUST 2023*



Access stats of Orphan Drugs (ODs) with trade name, with orphan designation in force as of 31 August 2023

ODs IN THE EU and SPAIN

202

Products with trade name and orphan designation

148

ODs with EMA marketing authorisation (MA)

126

ODs with National Code (NC) in Spain (85%)

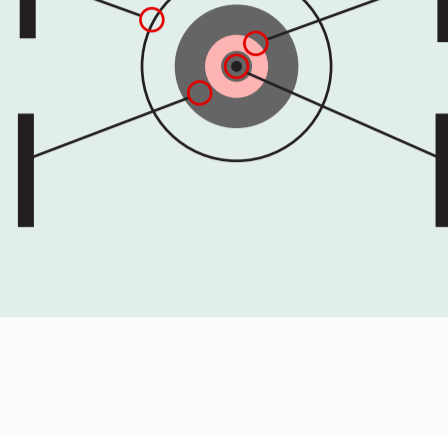
77

ODs funded by the NHS (52%)

MAY-AUGUST 2023

4 New orphan designations in the EU

5 New EMA marketing authorisation



2 ODs have obtained National Code in Spain

9 ODs have been funded by the NHS

ODs FUNDED IN SPAIN

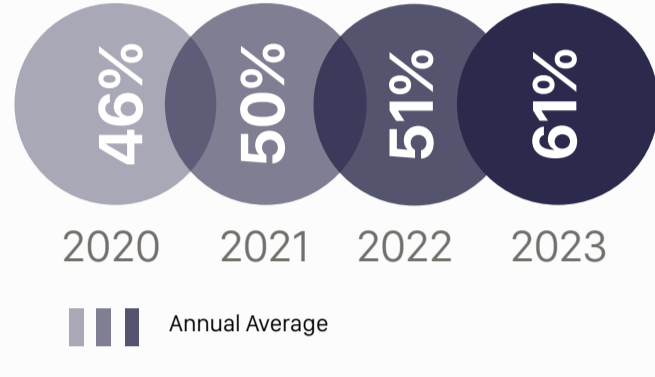
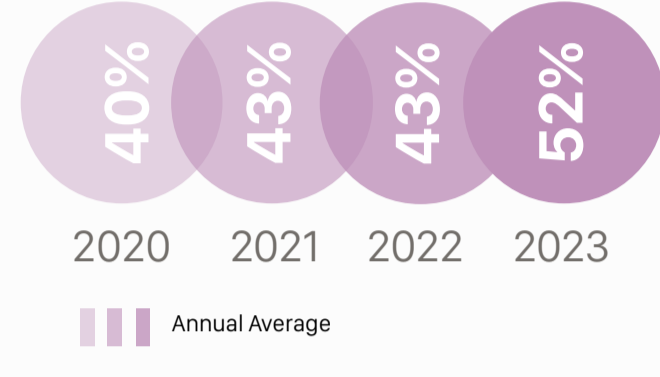
77 Orphan drugs are currently funded by the NHS

49% (38) ODs restrictedly funded (with restricted indications or unfunded indications)

% FUNDED

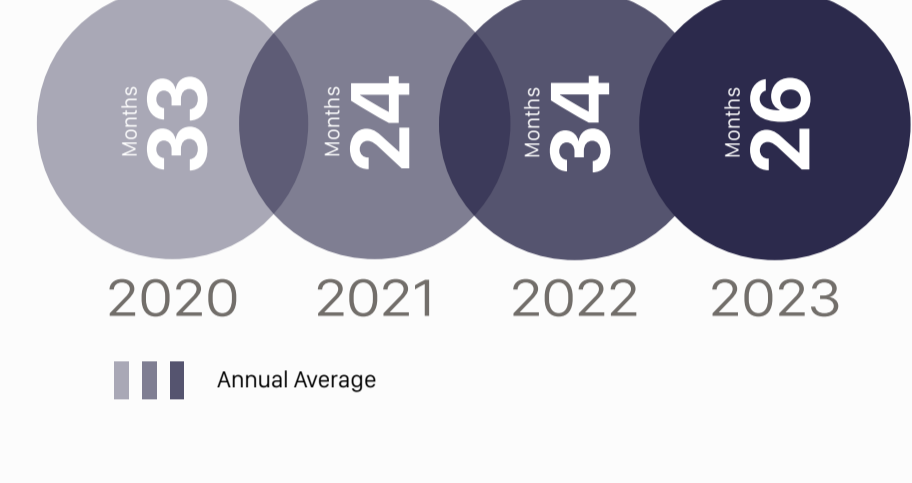
ODs with marketing authorisation funded by the NHS 2020 - 2023

ODs with NC funded by the NHS 2020 - 2023



AVERAGE WAITING TIME

Months between NC and incorporation into the NHS



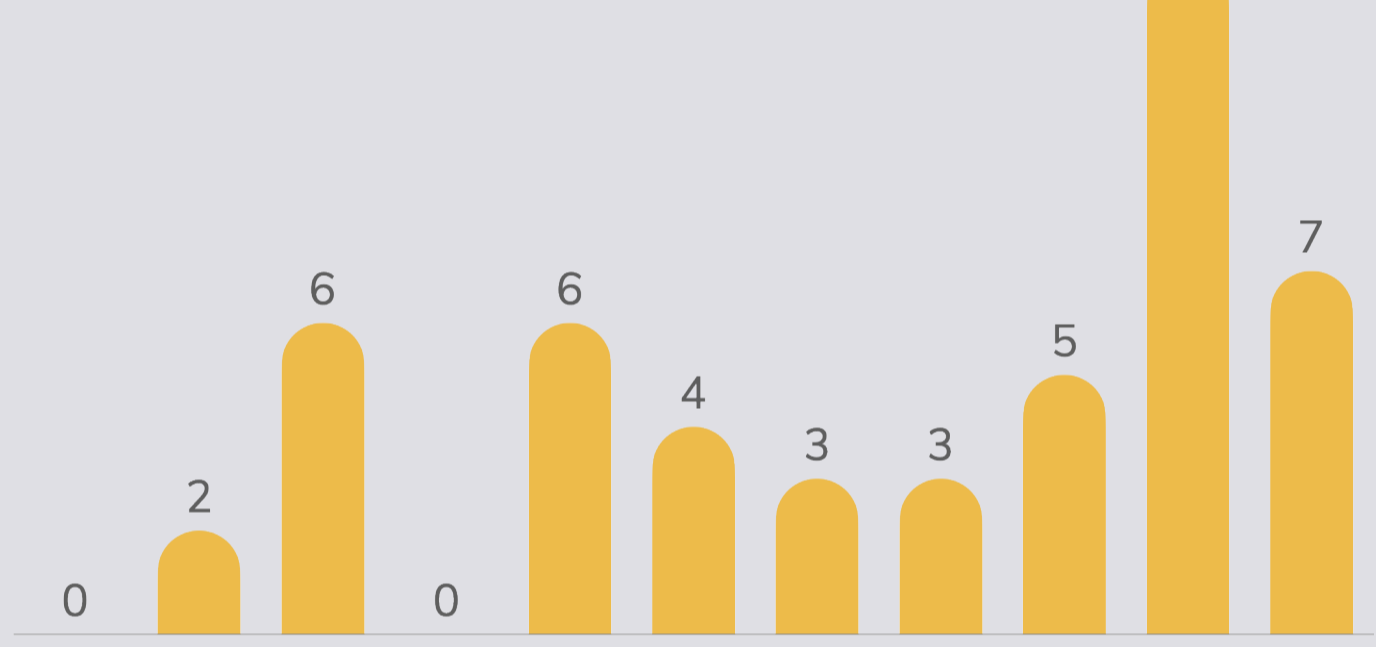
ODs NOT FUNDED IN SPAIN

49 Orphan Drugs with NC not funded by the NHS

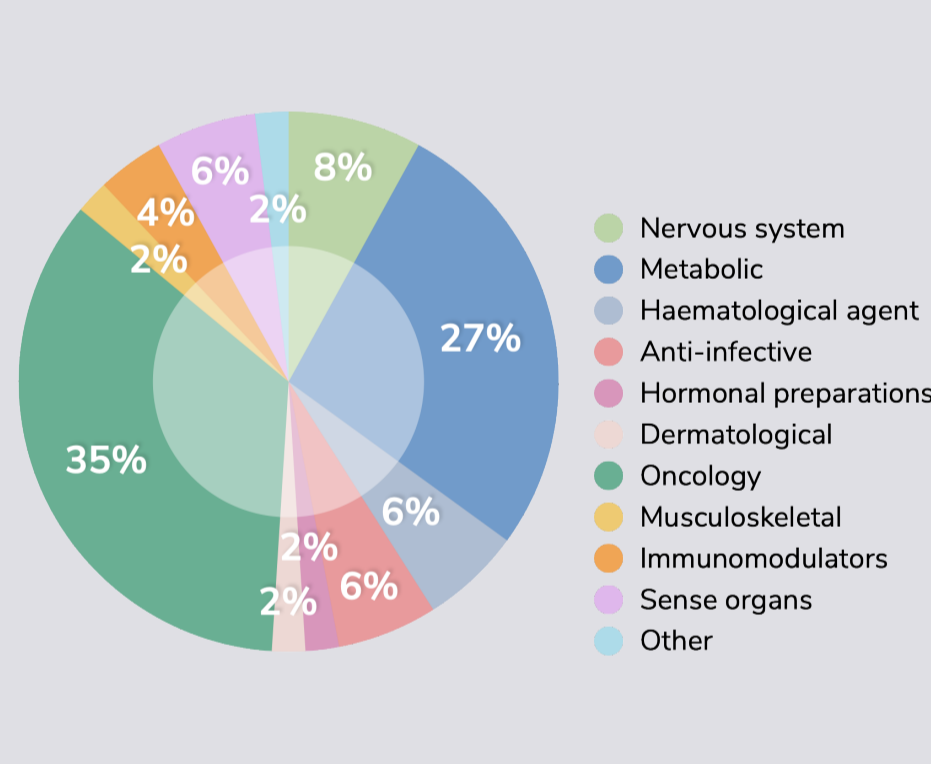
28 Not funded by resolution

21 Under study or without funding request

NUMBER OF ODs NOT FUNDED BY YEAR OF NC



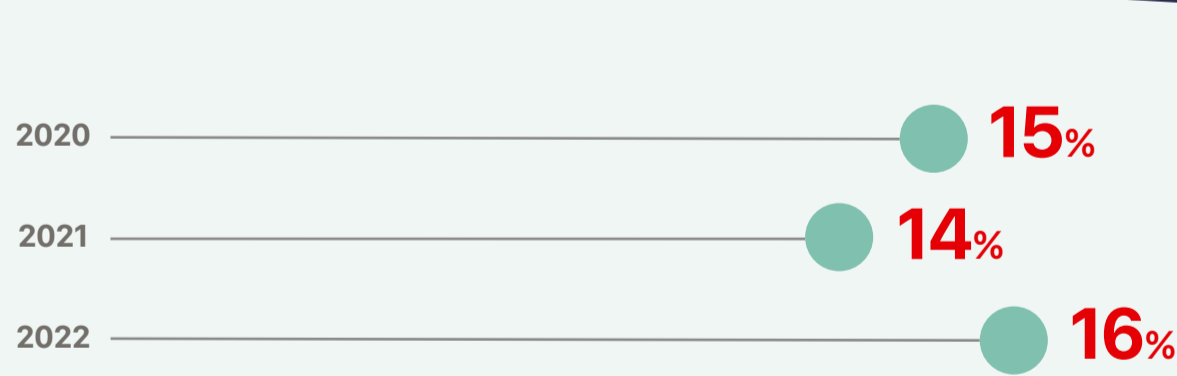
NUMBER OF ODs NOT FUNDED BY THERAPEUTIC AREA



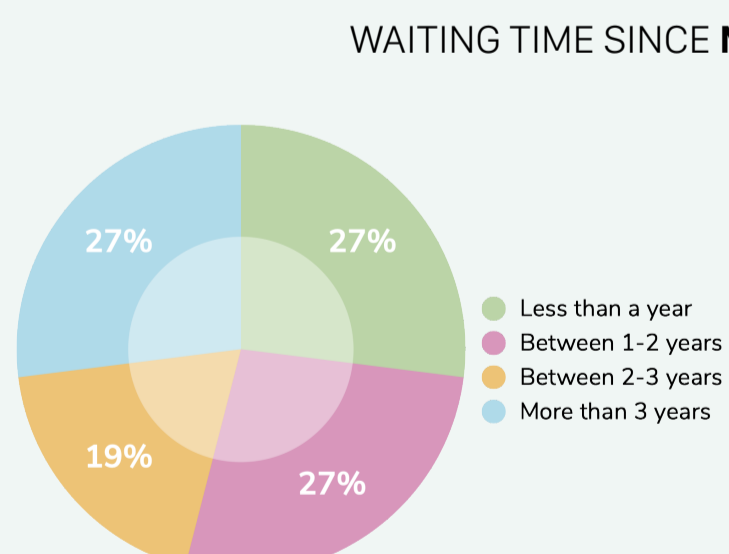
ODs WITH MA PENDING TO ARRIVE IN SPAIN

22 ODs WITH MA WITHOUT NC IN SPAIN

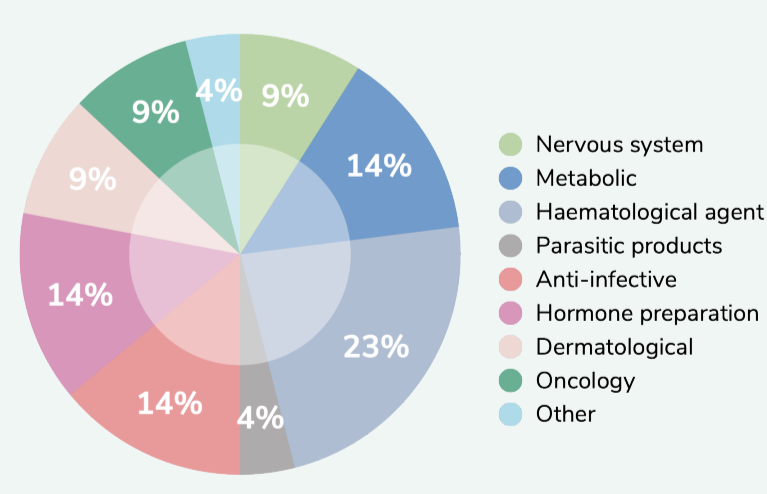
% ODs WITH MA WITHOUT NC



WAITING TIME SINCE MA



BY THERAPEUTIC AREA

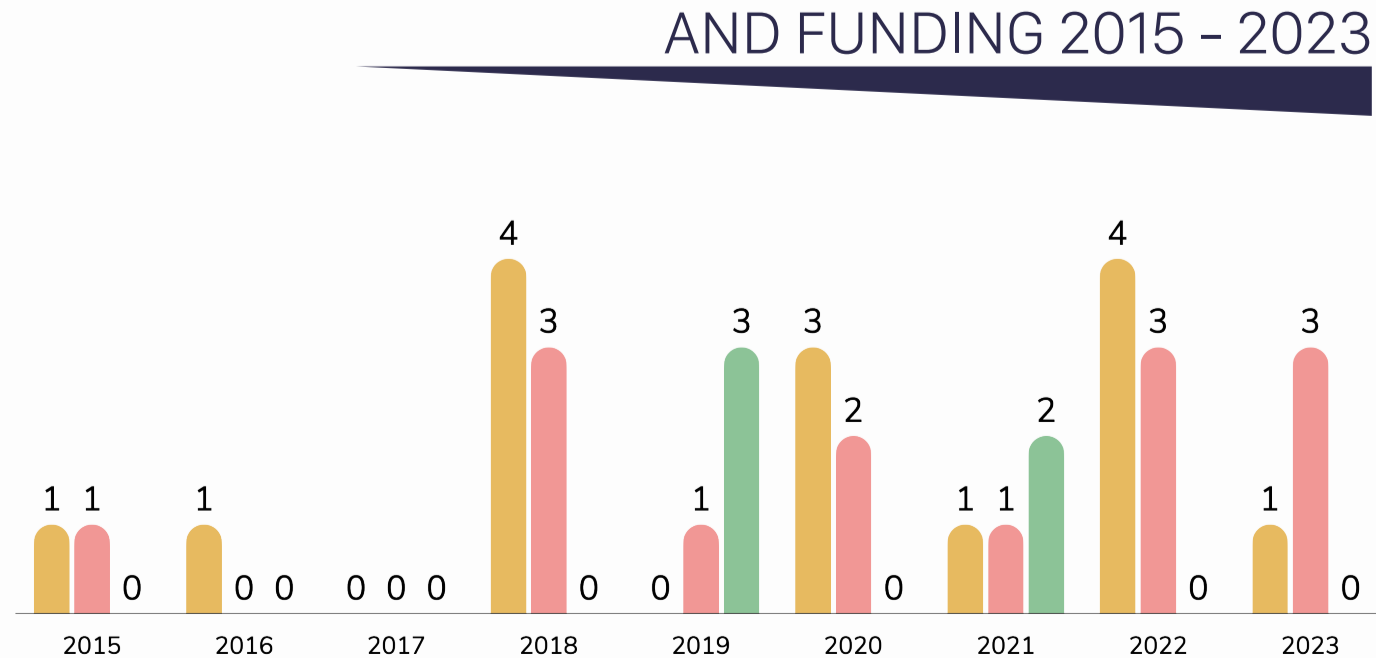


ADVANCED THERAPIES WITH ORPHAN DESIGNATION

As of 31 August 2023 there are:

15 Advanced Therapies with MA in Europe
14 With NC
5 Funded by the NHS

APPROVALS AND FUNDING 2015 - 2023



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 at 31 August 2023