

ORPHAN DRUGS IN SPAIN 2020 REPORT

Access status of all orphan drugs (ODs) with trade names, which have an orphan designation in force as of December 31, 2020

ODs in the EU in 2020

- 165 products** with trade name and positive orphan designation
22 new orphan designations, 73% more than in 2019
- 116 ODs** with marketing authorization
18 new authorizations, 13% more than in 2019

Out of the 116 ODs that currently have marketing authorization in the EU:

- 99** have received **National Code** in Spain (85%)
- 51** are **marketed** (44%)
- 46** are **financed** by the Spanish National Health System -SNS- (40%)



Between 2019 and 2020:

- ✓ **NC applications decrease by 6%**
- ✓ **National marketing authorizations decrease by 7%**
- ✓ **ODs financed by the SNS decreases by 4%**

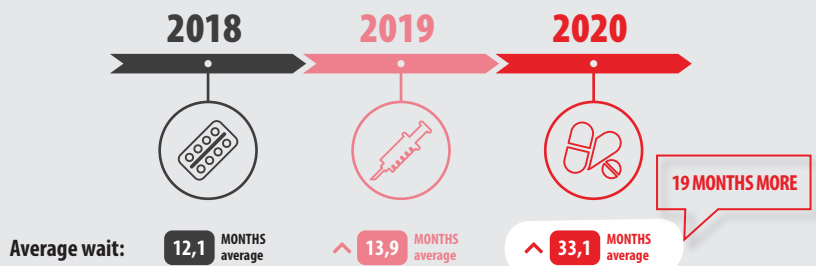


In 2020, 5 new ODs were financed in Spain:

- ✓ **45% less** than in 2019
- ⚠ **6 out of 10 ODs authorized** in Europe do **NOT** achieve public financing in Spain



AVERAGE TIME between the National Code and SNS financing



3 of the 5 ODs funded in 2020 took more than 4 years to obtain pricing and reimbursement



2020: 53 ODs. awaiting funding

No. of ODs awaiting funding with NC from 2011-2020 period

