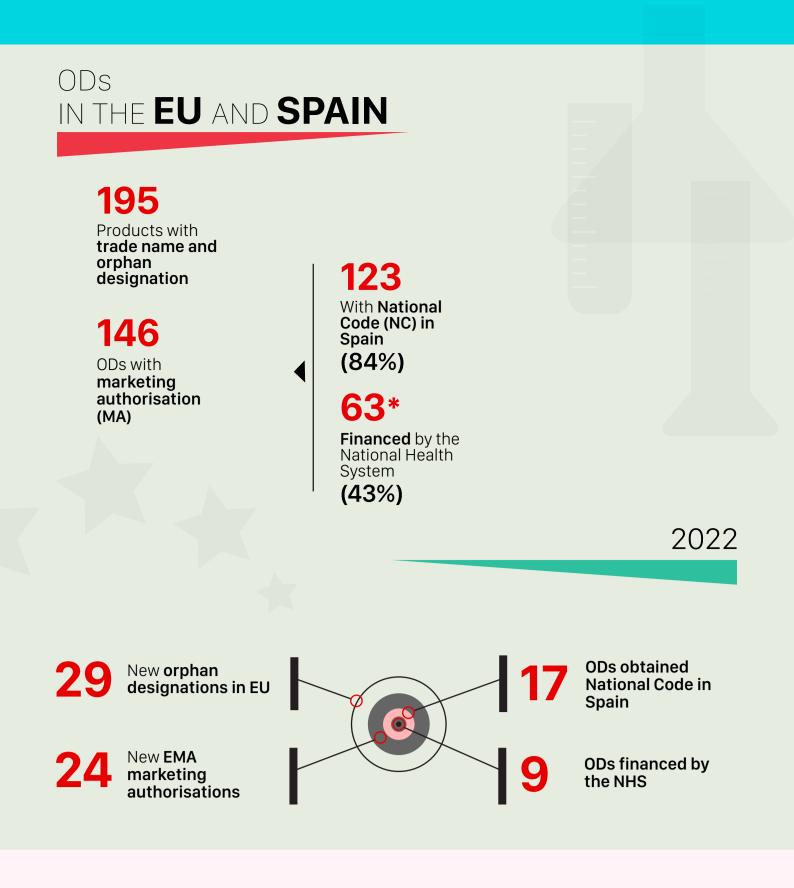
ORPHAN DRUGS IN SPAIN CCESS REPORT 022

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

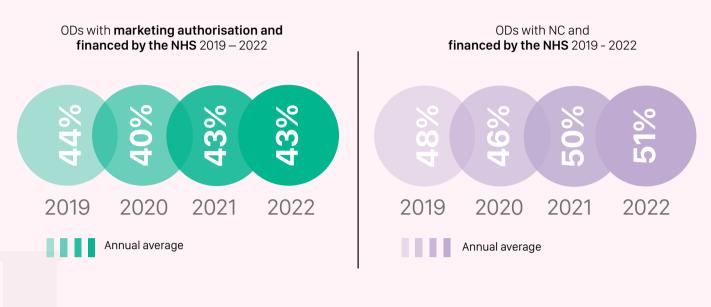




FINANCED ODs IN SPAIN







AVERAGE WAITING TIME



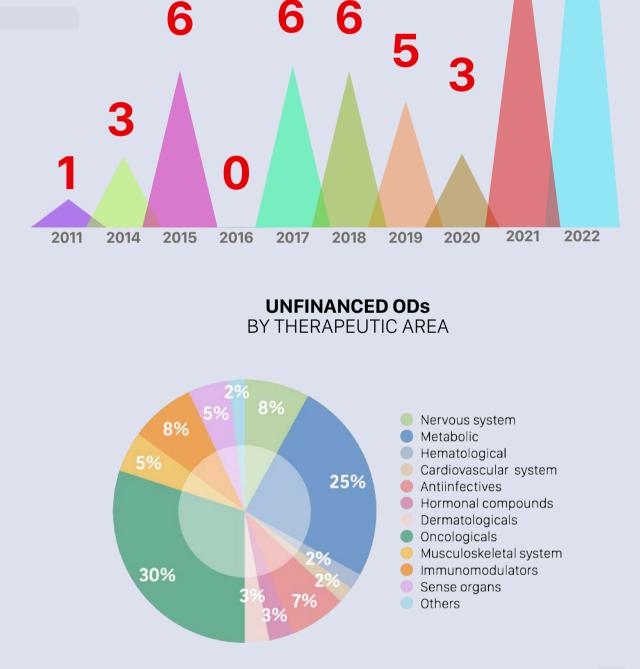
ODs **UNFINANCED IN SPAIN**

- **60** Orphan drugs with National Code not financed by the NHS
- **32** Not financed by resolution
- **28** Under study or without funding request

NO. OF UNFINANCED ODs PER NATIONAL CODE YEAR

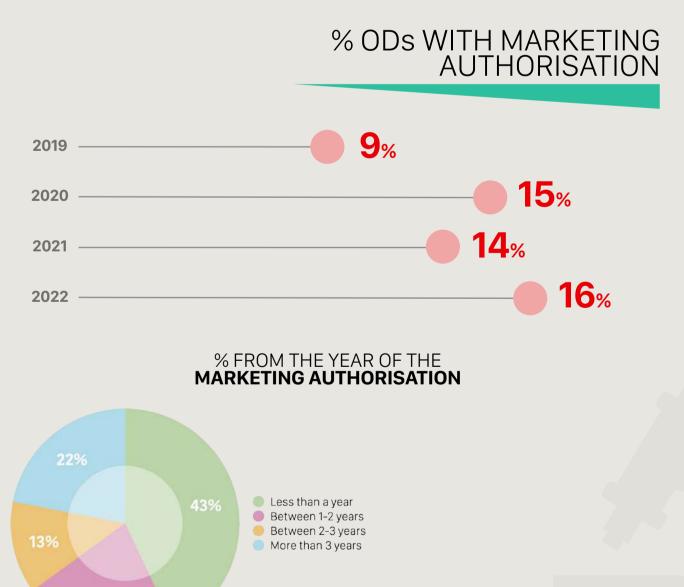
О

17 13



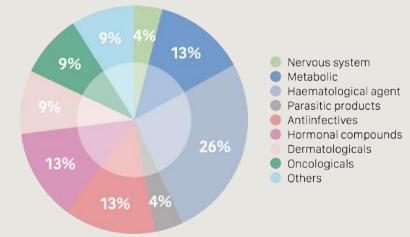
ODS WITH **MARKETING AUTHORISATION** WAITING FOR ARRIVAL TO **SPAIN**







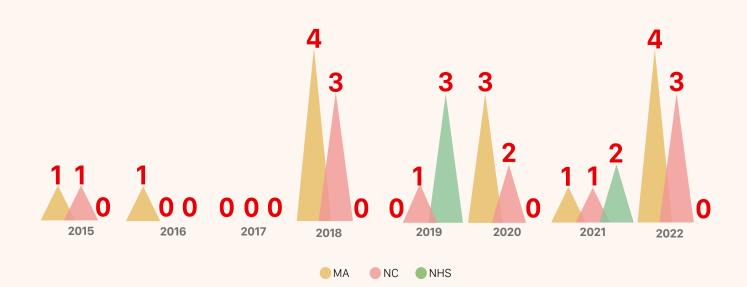
BY THERAPEUTIC AREA



ADVANCED THERAPIES WITH ORPHAN DESIGNATION



APPROVALS AND FINANCING 2015 - 2022



* Onivyde® is included in the recount of medicines financed by the NHS as of 31/12/2022. During December 2022, Onivyde® was reinstated in Nomenclátor. This product was financed in 2018, but was withdrawn in 2019.

Note: for the preparation of this report, it was not possible to consider 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 cannot be consulted in public sources.



linkedin.com/company/aelmhu

The sources relied on for this report are the European Medicines Agency (EMA), the Community Register of orphan medicinal products, the Spanish Agency for Medicines and Health Products (AEMPS) and the Ministry of Health.

(in)