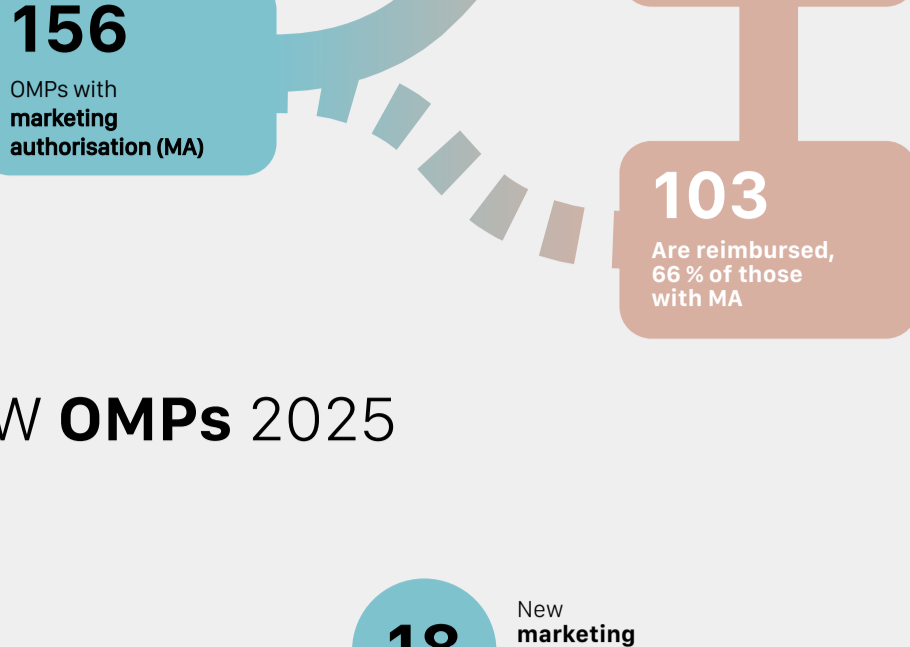


Market access status of all Orphan Medicinal Products (OMPs) with trade names and with Orphan Designation (OD) in force, as of 31 December 2025

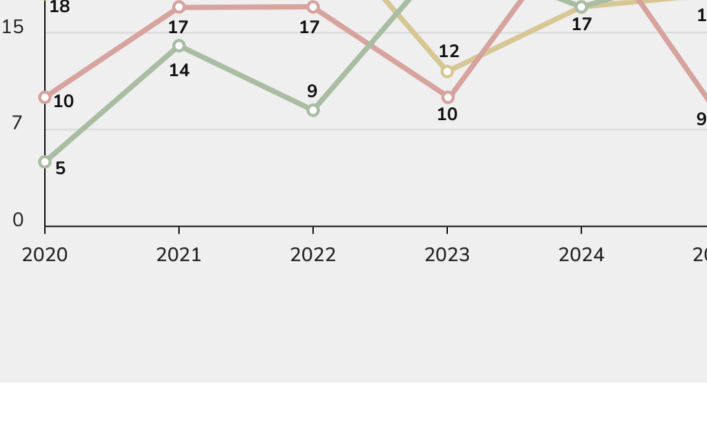
→ OMPs IN THE **UE** AND **SPAIN**



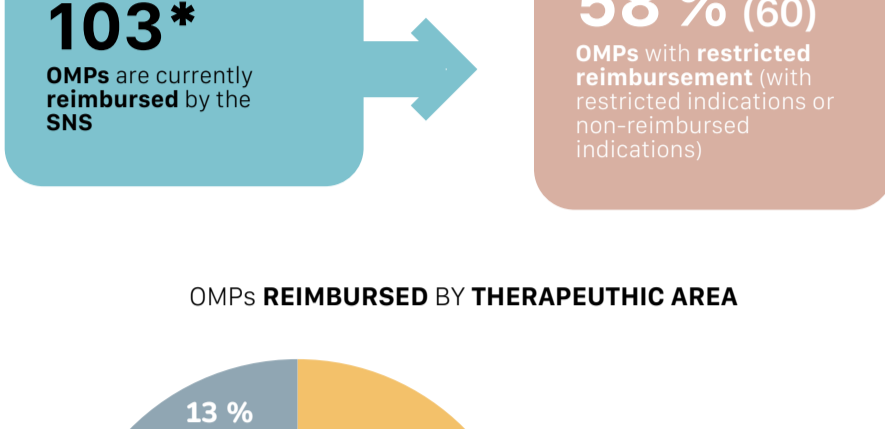
→ NEW OMPs 2025



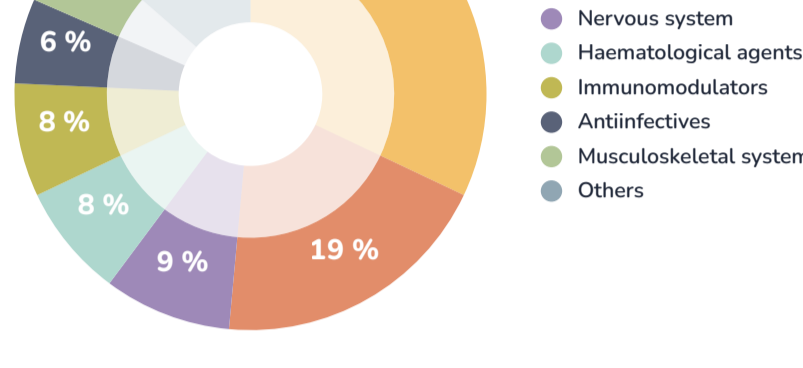
→ INDICATORS OVERVIEW 2020 - 2025



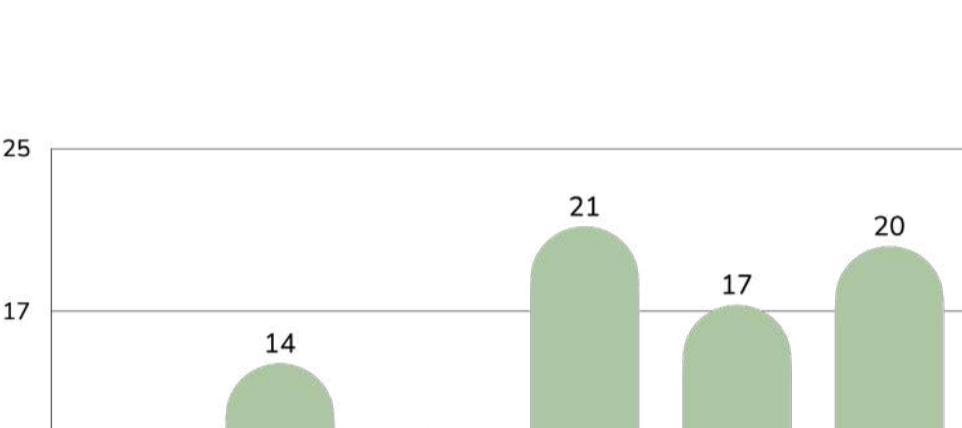
→ OMPs REIMBURSED IN SPAIN



OMPs REIMBURSED BY THERAPEUTIC AREA



→ N° OF OMPs REIMBURSED IN SPAIN 2020 - 2025



→ % REIMBURSED



→ AVERAGE WAITING TIME



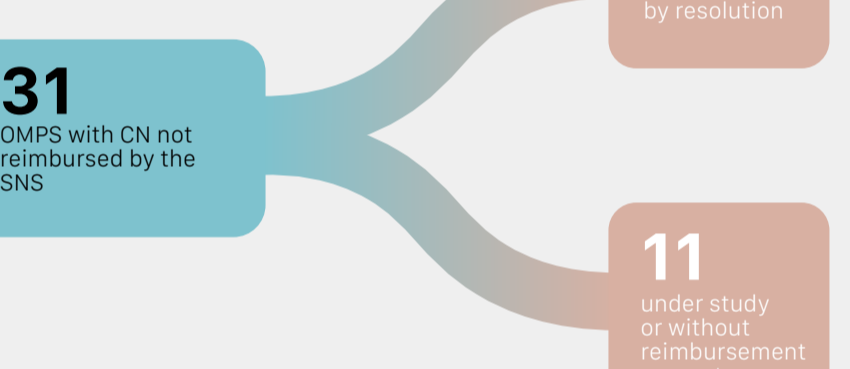
→ OMPs NOT REIMBURSED IN SPAIN



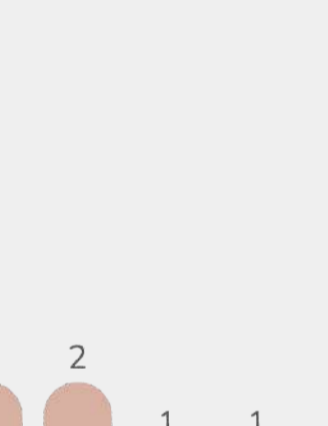
NUMBER OF OMPs NOT REIMBURSED BY YEAR OF NC



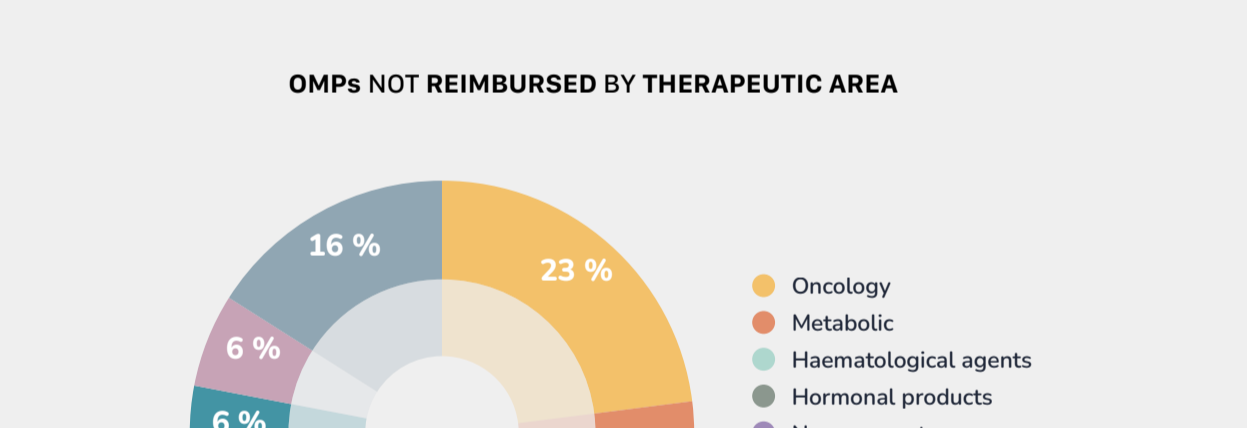
OMPs NOT REIMBURSED BY THERAPEUTIC AREA



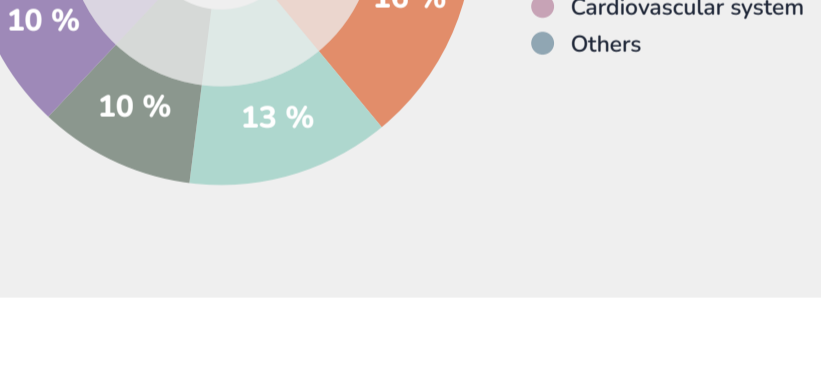
→ OMPs WITH MA PENDING TO ARRIVE IN SPAIN



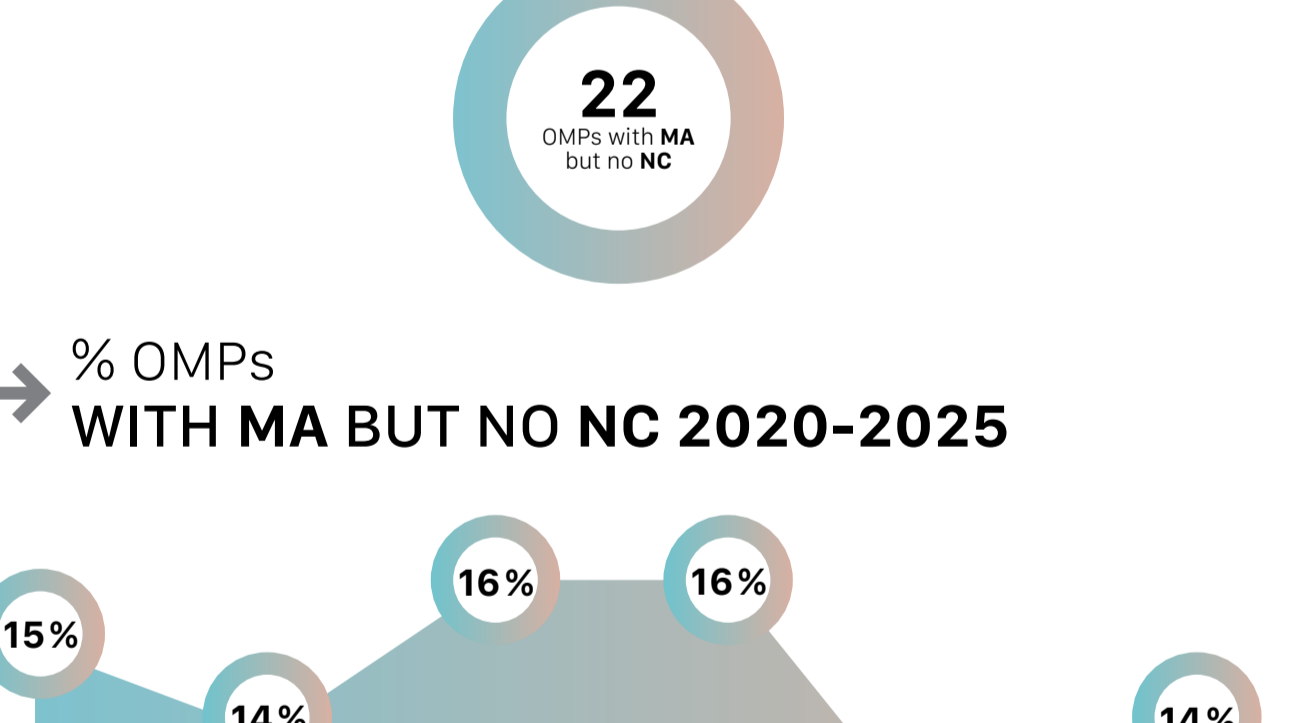
→ % OMPs WITH MA BUT NO NC 2020-2025



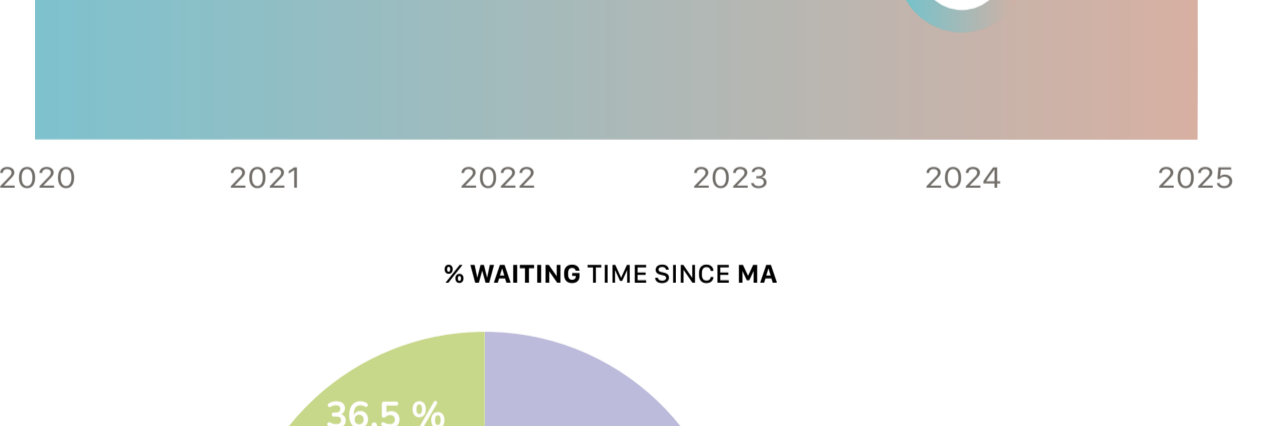
% WAITING TIME SINCE MA



→ ADVANCED THERAPY MEDICINAL PRODUCTS (ATMPs) FOR RARE DISEASES



→ ATMPs WITH MA, NC AND REIMBURSEMENT SINCE 2016



Note 1: Due to the fact that the information is not publicly available, this report does not include those medicines under the 'special situations' set out in Royal Decree 1015/2009, about compassionate use, use in conditions other than those authorised, or access to foreign medicines (available here: <https://www.boe.es/eli/es/rd/2009/06/19/1015>).

Note 2: The values in the graph referring to advanced therapies with marketing authorisation, national code and reimbursed by SNS, are not cumulative.

Note 3: The values represented in the graphs are usually rounded to whole numbers for ease of understanding. Exceptionally, decimals have been included when necessary to maintain the consistency and accuracy of the data analysed.

* Data aggregated up to 31 December 2025.

** The 15 advanced therapies with OD and MA would be included in the total of 221 OMPs with OD and the 156 OMPs with MA, as they are advanced therapies with a trade name.

Glossary:

- OD (Orphan designation)
- OMPs (Orphan medicinal products)
- ATMPs (Advanced Therapy Medicinal Products)
- MA (Marketing Authorisation)
- NC (National Code)
- SNS (Spain's National Health System)