From Clinical Assessment to Drug Reimbursement in Spain: Current Timelines and Potential Impact from the Joint Clinical Assessment

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OBJECTIVES

- Assess the **time to reimbursement** in Spain for centrally authorized drugs and explore the impact of the new European Joint Clinical Assessment (JCA).

METHODS

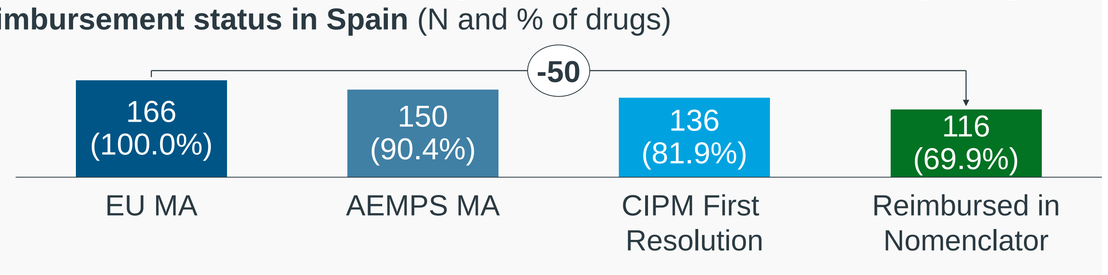
- JCA timelines were analysed using the JCA procedural implementing act and EU HTA regulation 2011/2282. The EMA procedural timetable for initial (full) market authorization application assessments were analysed using the relevant EMA documentation [1-3].
- A **list with human medicines** receiving a marketing authorization (MA) for the European Union (EU) during the period **January 2019 to December 2022** was retrieved from the EMA website [4]. Drug's name, active substance, therapeutic area, application type, and date of the MA approval by the European Commission were collected.
- To assess the reimbursement status in Spain, the **IQVIA Market Access Tracker** [5] was used, namely including:
  - The date of **national codes** (NC) issued by the Spanish Agency of Medicines and Medical Devices (AEMPS) until 19/10/2022 [6]. Once there is an EU MA, the **AEMPS must be notified** of the company´s interest in marketing the drug in Spain and submit the NC application. The **reimbursement process** will start only after the NC is issued.
  - Agreements from the Spanish Interministerial Commission on Prices and Health Products (CIPM) published from January 2019 to April 2024 [7]. The **NC**, **drug's name**, **active substance, decision adopted**, **criteria** stated for decision, and **special funding conditions**, if applicable, were collected for this purpose.
  - The date of inclusion of the drugs in the official National Health System (NHS) reimbursement list – *Nomenclátor* – until 26/06/2024 [8].
- The following metrics were assessed:
  - The **number of drugs** receiving an EU MA during the studied period which: **a)** have received a NC by AEMPS; **b)** have been assessed by the CIPM and have a published resolution (positive or negative); **c)** have received a positive reimbursement resolution from the CIPM; **d)** have been included in the *Nomenclátor* and are thus officially reimbursed by the Spanish NHS.
  - The **time since the EU MA** is issued until the drug is reimbursed in Spain (for those reimbursed).
  - The **cases when a drug received** initially a negative reimbursement resolution by the CIPM and later received a positive resolution, and the time between both decisions.
  - Data was **stratified by therapeutic** area and EU MA characteristics.

RESULTS

Number of drugs with a positive reimbursement decision

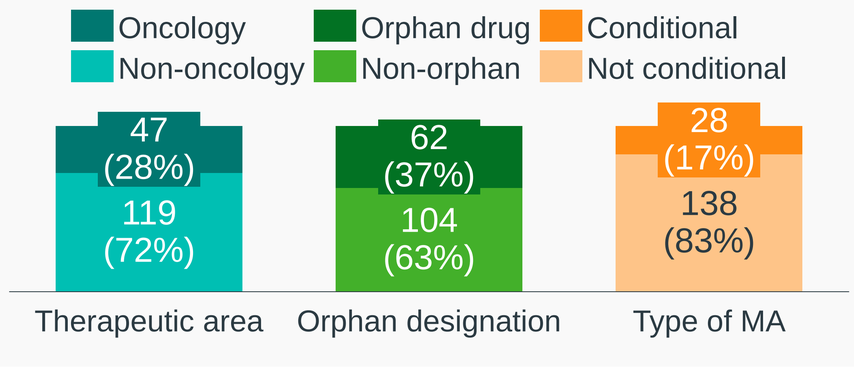
- In the study period, **166 new drugs received an EU MA**. Most (150, 90.4%) obtained a NC and 116 (69.9%) were reimbursed (**Figure 1**).

Figure 1 – Number of new drugs with an EU MA and their pricing and reimbursement status in Spain (N and % of drugs)



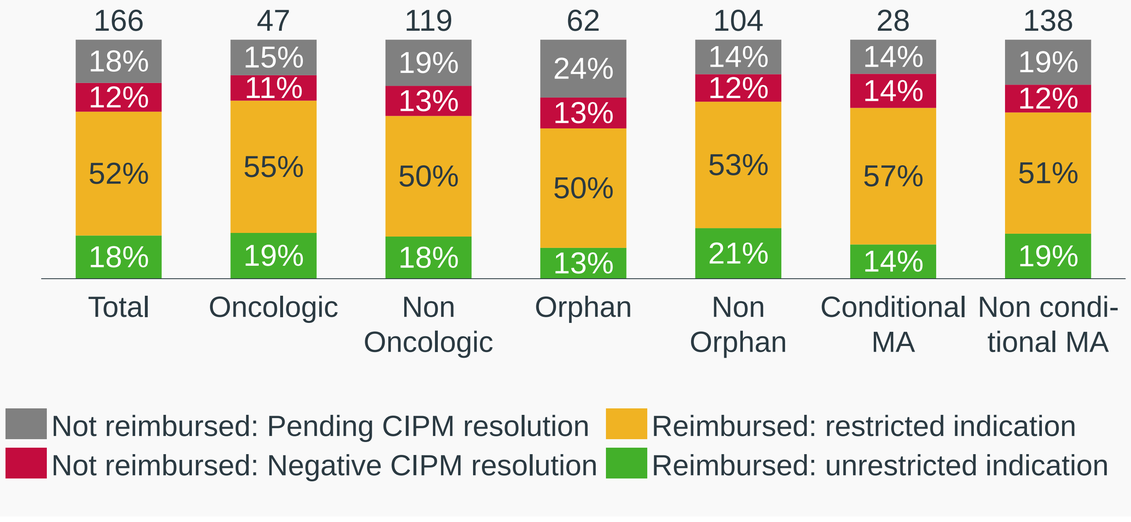
- Out of the medicine authorization, 47 (28%) were in **oncology**, 62 (37%) were **orphan** drugs and 28 (17%) had a **conditional marketing** authorization (**Figure 2**).

Figure 2 – Description of the list of analyzed medicines



- **Oncologic drugs** had a higher proportion of positive reimbursement decisions, 74.5%, compared with non-oncologic ones, 68.1% (**Figure 3**). **Drugs receiving a conditional MA** displayed a higher share of negative reimbursement resolutions.

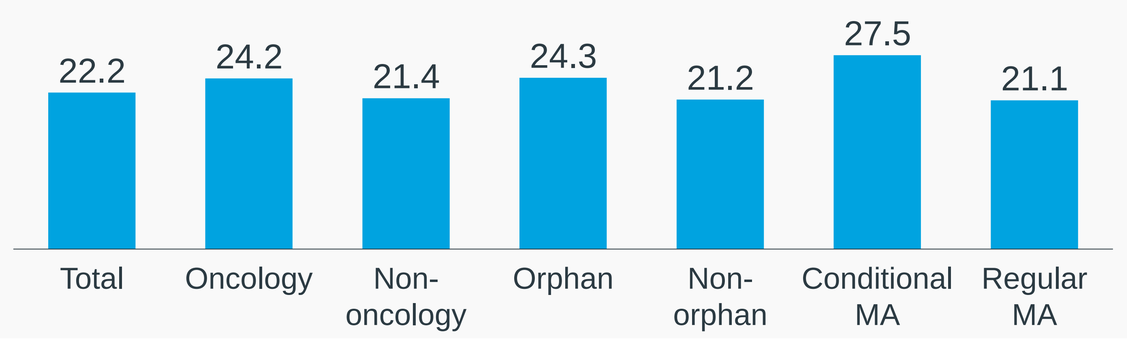
Figure 3 – Reimbursement status in Spain of drugs with an EU MA by characteristics (N and % of drugs)



Time since EU MA to reimbursement in Spain

- The average time from centralized MA to NC was 5.7 months. Additionally, it took 16.7 months to reach the first CIPM resolution and 22.2 months for full reimbursement.
- The time (months) to NC varied across oncology (4.4), non-oncology (6.2), and orphan (6.6) drugs. The time to the first CIPM resolution varied across oncology (14.9), non-oncology (17.5), and orphan (18.2) drugs.
- The time (months) to reimbursement varied across oncology (24.2), non-oncology (21.4), and orphan (24.3) drugs (**Figure 4**).

Figure 4 – Mean time to reimbursement in Spain since EU MA (months)



- With the JCA, the clinical assessment report will be published 30 days after MA. Then, the AEMPS would publish its Clinical and Economic HTA within 20 days, reducing national times outside of the JCA by 40 days. Early discussions between the Ministry of Health and medicine developers, along with early preparedness from the developers, would enable further reductions in the time required for access.

CONCLUSION

By June 2024, Spain had reimbursed two-thirds of EMA-authorized medicines (01/2019-12/2022) in an average of 22.2 months. By providing clinical assessment results within one month, the JCA offers the possibility to reduce local timelines for value dossier submission and assessment at least 1.5 months

REFERENCES

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