AUTHORISATION AND FINANCING SITUATION IN SPAIN OF THE NEW MEDICINES AND INDICATIONS AUTHORISED BY THE EUROPEAN COMMISSION IN THE PERIOD 2021-2023

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INTRODUCTION AND OBJECTIVE

- Making new medicines affordable has been recognized as a key policy goal by the Organisation for Economic Co-operation and Development (OECD) and the European Union (EU) countries. Ideally, several dimensions should be considered to properly monitor medicine access in each country, such as availability, affordability, accessibility, and acceptability. However, country-specific information is gathered from diverse sources, each differing in quality and confidentiality.[1]
- Our study aimed to evaluate key milestones and the timing of different stages leading to Spanish reimbursement for new medicines and indications (NMI) authorised by the European Commission (EC) in the period 2021-2023.

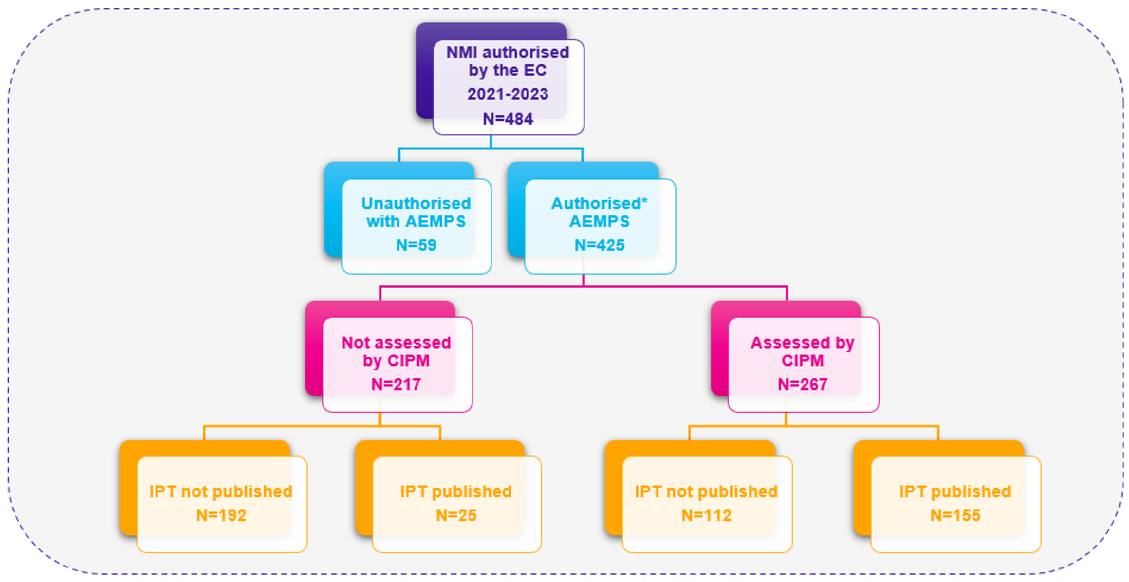
METHODS

- NMI authorised by the EC through the centralised procedure between 2021 and 2023 were evaluated. Generic medicines were excluded.[2]
- The data for the analysis were obtained from the European Medicines Agency (EMA), the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), or the Spanish Ministry of Health websites.[3-5]
- The main variables evaluated were:
  - ✓ Total number of NMI authorised by the EC.
  - ✓ AEMPS authorisation status and time until AEMPS authorisation.
  - ✓ Reimbursement status and time to reimbursement.
  - ✓ Spanish Therapeutic Positioning Reports (IPT) process (number of reports published, process timings, positioning conclusions, etc.).
- A descriptive analysis of these variables was conducted.

RESULTS

- Between 2021 and 2023, 484 NMIs were authorised by the EC (Figure 1).
- Forty-three percent (210) were new medicines. Of these, 76% (159) were authorised by AEMPS. Time from EC authorisation to AEMPS authorisation was 3.7 months.

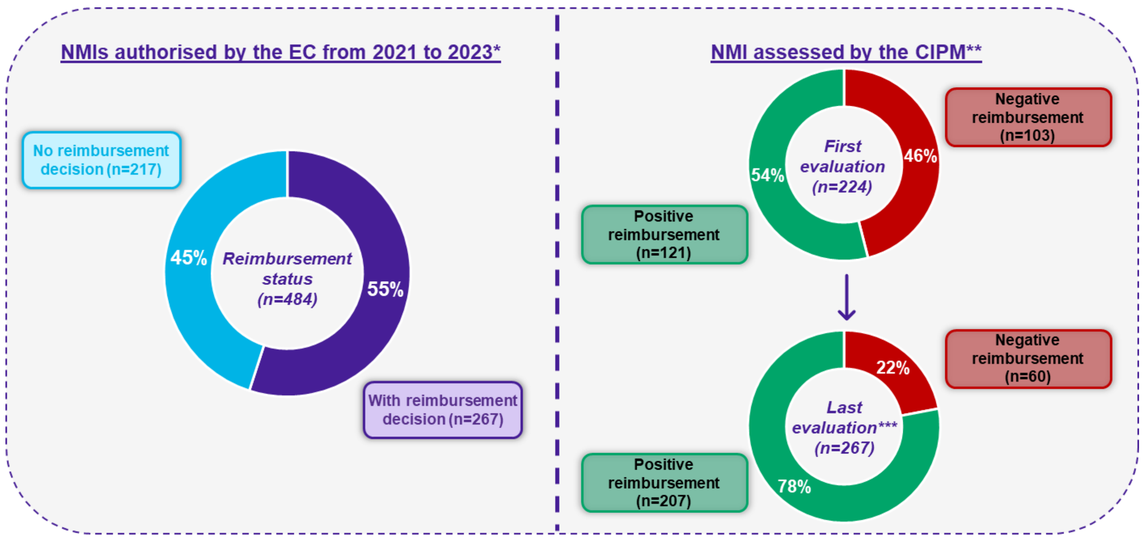
Figure 1. NMIs authorised by the EC by centralised procedure from 2021 to 2023



Abbreviations: AEMPS = Agencia Española de Medicamentos y Productos Sanitarios; CIPM= Comisión de Precios de Medicamentos; EC= European Commission; IPT = Therapeutic Positioning Reports; NMI = New Medicines and Indications. *In case of new indications, EC registration status was considered.

- Of the 484 NMIs authorised by the EC, 55% (267) were assessed by the CIPM. Information on P&R history (covering from the first to the last CIPM evaluation) was only available for 224 NMIs (84%) (Figure 2).

Figure 2. Reimbursement status and number of evaluations carried out by the CIPM



Abbreviations: CIPM= Comisión de Precios de Medicamentos; EC= European Commission; NMI = New Medicines and Indications. *Percentage of reimbursement calculated on NMIs authorised by the EC.**The date of the first CIPM assessment is available for 224 of the 267 NMIs with a reimbursement decision.***The latest assessment refers to the most recent assessment for which data are available (may include from the first CIPM meeting to subsequent meetings).

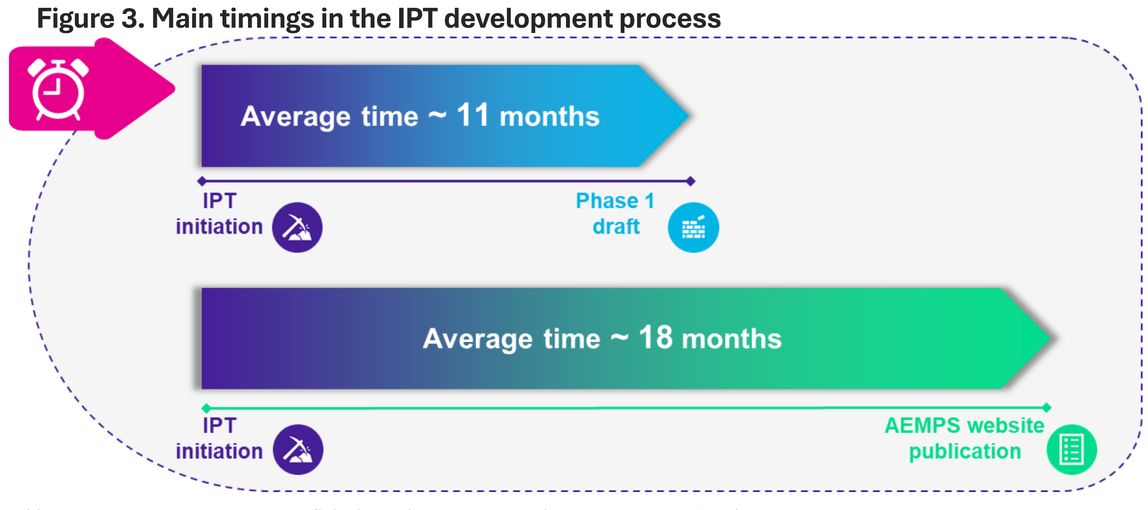
Table 1. NMIs assessed by the CIPM with data from the first to the last evaluation*

		NMI with any opinion in the first assessment	NMI with positive opinion at first assessment	NMI with a negative opinion in the first assessment
Number of evaluations	N (%)	224 (100%)	121 (54%)	103 (46%)
Time until opinion		10.3 months	9.8 months	10.9 months
% of allegations		37%	11%	67%
Average number of evaluations		1.4	1.1	1.8
≥3 evaluations		8 (3.6%)	1 (0.8%)	7 (6.8%)

Abbreviations: NMI = New Medicines and Indications; CIPM= Comisión de Precios de Medicamentos. *Time from authorisation by the AEMPS to the CIPM meeting in the case of new medicinal products, time from authorisation by the EC to the CIPM meeting in the case of new indications. This analysis was carried out for NMIs where P&R history was available, covering the first to the last CIPM assessment (n=224/267).

- A positive resolution was received by 121 NMIs (54%) on the first evaluation, with an average access time of 9.8 months (Table 1).
- NMIs had an average of 1.4 (range: 1-5) CIPM evaluations (Table 1).
- The most frequently applied financing conditions were SEGUIMED (85%) and annual reviews of sales and prices (76%).
- The main reason for not financing was a high budgetary impact (74%).

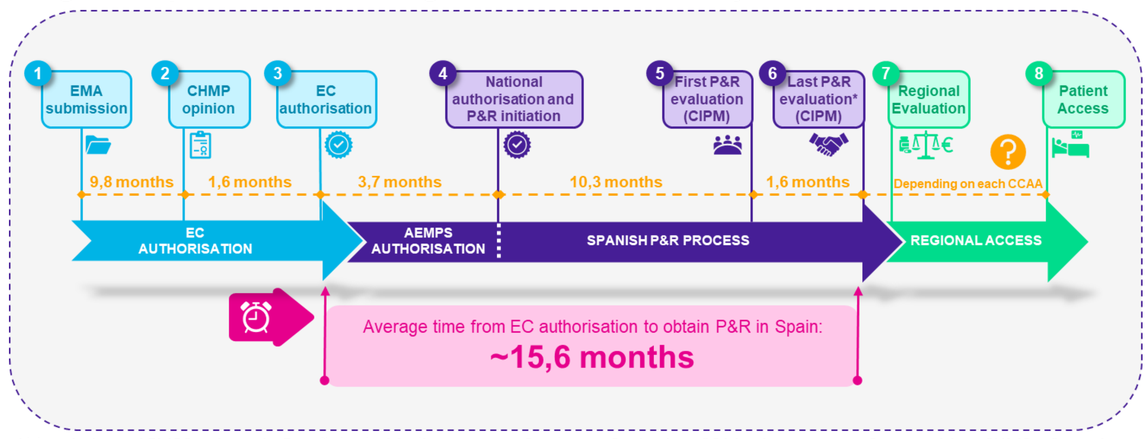
Figure 3. Main timings in the IPT development process



Abbreviations: AEMPS = Agencia Española de Medicamentos y Productos Sanitarios; IPT = Therapeutic Positioning Reports.

- One hundred and eighty NMIs (37%) had a published IPT with an average time from initiation to Phase 1 draft of 11 months and to final publication of 18 months (Figure 1,3).
- Most of the IPT published were for oncology medicines (45%; n=81).
- Forty-eight (27%) of all IPT published had conclusions that restricted the approved indication by recommending other drugs preferably.

Figure 4. Spanish access timings for NMIs authorised by the EC from 2021 to 2023



Abbreviations: AEMPS = Agencia Española de Medicamentos y Productos Sanitarios; CCAA= Autonomous Communities; CHMP= Committee for Medicinal Products for Human Use; CIPM= Comisión de Precios de Medicamentos; EC= European Commission; EMA= European Medicines Agency; P&R= price and reimbursement. *The last evaluation refers to the most recent assessment for which data are available (may include from the first CIPM meeting to subsequent meetings).

- The average time from EC authorisation to obtain the P&R decision in Spain was 15.6 months (Figure 4).
- After national reimbursement, the time required to achieve regional access must also be considered as an additional step before patients can access NMIs. However, details regarding the timing and steps involved in the regional access process are not publicly available.

CONCLUSIONS

Information on the main timelines and stages that condition access to NMIs in different European countries is crucial to better understand this process. Consequently, it is essential to identify factors that may influence the availability and accessibility of NMIs in local markets, so better strategic decisions can be made. Currently, the lack of public data on regional access hinders the estimation of the total duration of the Spanish access process.

REFERENCES:

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