Reimbursement status of centrally authorized drugs in Spain per therapeutic area and orphan designation

HPR204

Mafalda Carmo[1], Laia Aguilar Sugrañes[1], Ariadna Olivella[1], Aaron Aires[1], María Lloret Avellá[1], Marco Pinel[2], Daniel Callejo[2]

1. IQVIA, Barcelona, Spain, 2. IQVIA, Madrid, Spain.

OBJECTIVES

- To assess the reimbursement status and time to reimbursement in Spain of drugs authorized by the European Medicines Agency (EMA).

METHODS

- A list of human medicines centrally authorized from 01/2018-12/2021 was retrieved from the EMA website [1]. Medicine name, therapeutic area, orphan designation, and marketing authorization (MA) date and type were collected. The list is the same as in EFPIA Patients W.A.I.T. Indicator 2022 Survey [2].
- To assess the reimbursement status in Spain, the IQVIA Market Access Tracker was used [3]*, namely including:

i. The date of national codes (NC) issued by the Spanish Agency of Medicines and Medical Devices (AEMPS) until 29/10/2023 [4]. 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.

ii. Minutes from the Spanish Interministerial Commission on Prices and Health Products (CIMP) meetings from 01/2018-10/2023 were extracted to analyze the reimbursement resolutions [5]. National code, medicine name, resolution adopted, criteria stated for decision, and special funding conditions were collected for this purpose.

iii. A product was considered reimbursed once it was included in the national reimbursement list (*Nomenclátor*) [6]. The rate of reimbursement, measured by the number of medicines in the national reimbursement list as of 29th October 2023 (including products with restricted indications), and the time since centralized marketing authorization to inclusion in the national reimbursement list were estimated for the total sample and for several subcategories.

RESULTS

- A total of 168 new medicines were authorized by the EMA in the study period, of which 46 in oncology and 122 in other therapeutic areas. One-third were orphan drugs (Fig.1).

Figure 1. Description of the list of analysed medicines

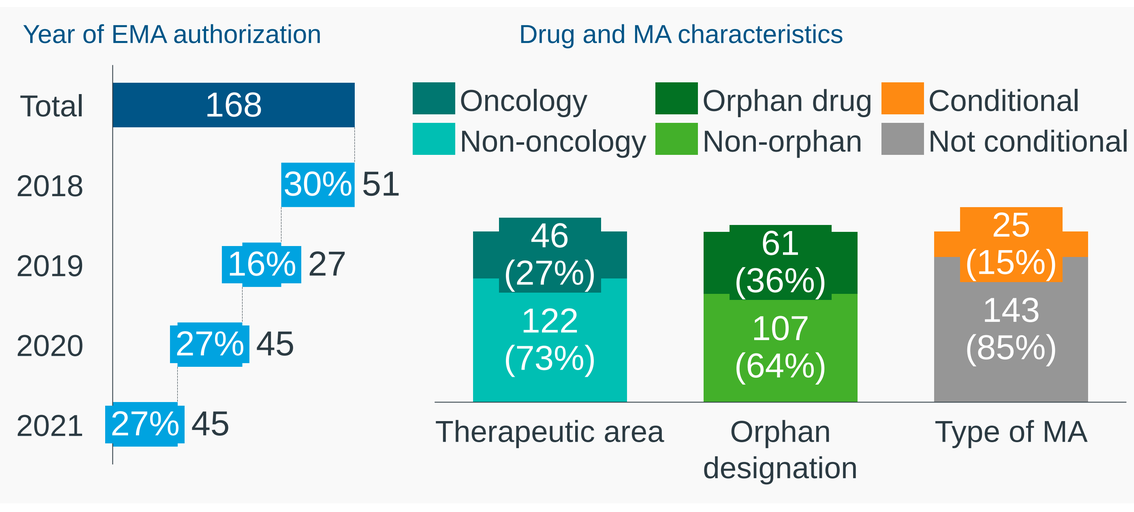
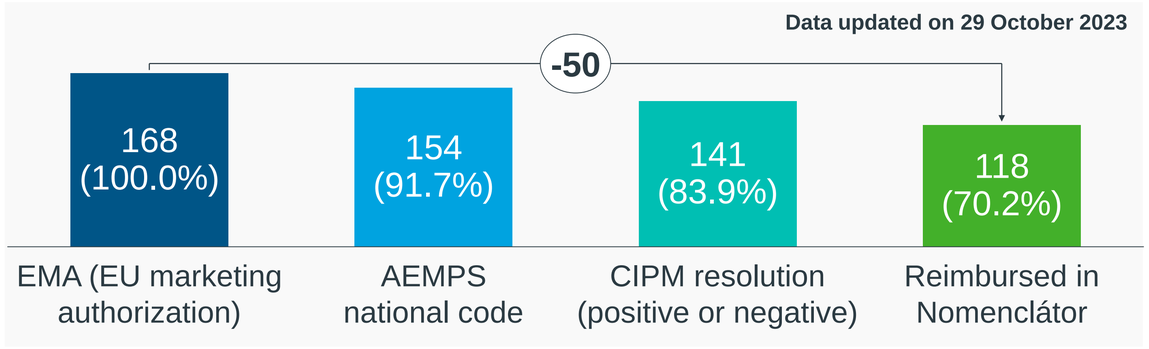
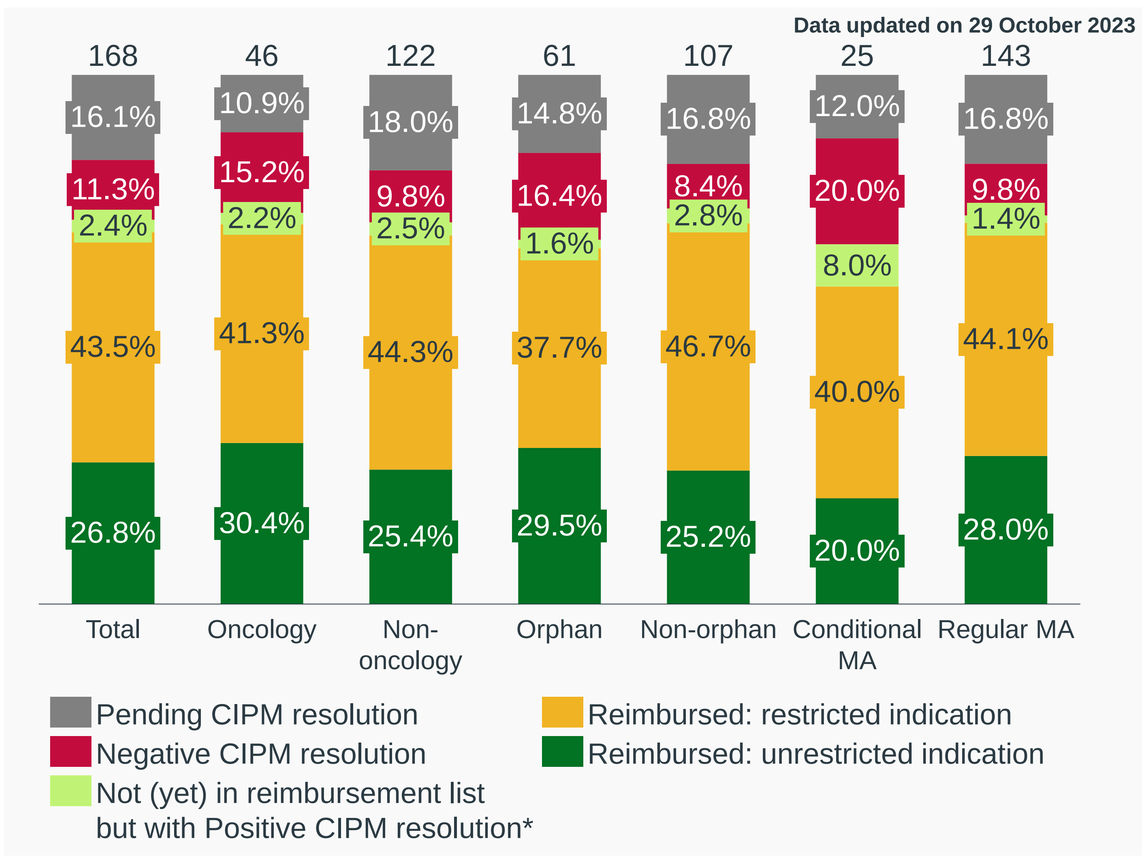


Figure 2. Status in Spain of the EMA authorized drugs (N, % of drugs)



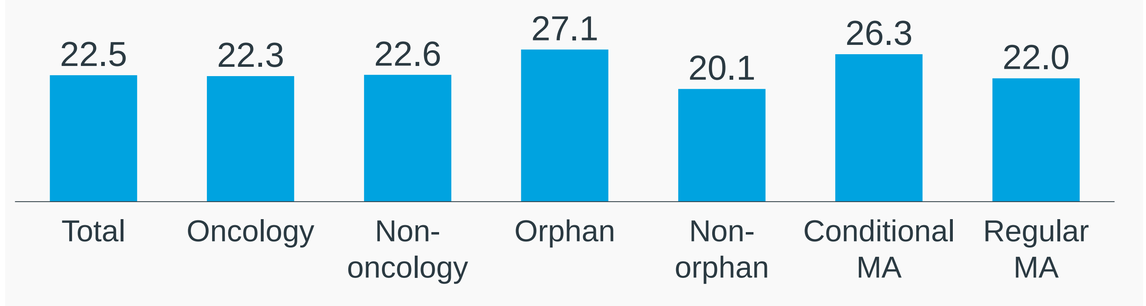
- Most (154, 91.7%) had a valid NC and were reimbursed (118, 70.2%) (Fig.2). Specifically, 26.8% were fully reimbursed, 43.5% were partially reimbursed (restricted indication), 11.3% received a negative reimbursement resolution (Fig.3), 8.3% had no NC, 7.7% had a NC but were pending a reimbursement resolution, and 2.4% had a positive reimbursement resolution by the CIPM but were not yet in the reimbursement list.

Figure 3. Reimbursement status in Spain of the EMA authorized drugs by characteristics (N, % of drugs)



- The rate of reimbursement was 71.7% for oncology, 69.7% for non-oncology, and 67.2% for orphan drugs (Fig.3). Drugs receiving a conditional MA displayed a higher share of negative reimbursement resolutions.
- Mean time to reimbursement for all the medicines reviewed was 22.5 months, being higher for orphan drugs and for drugs who received a conditional MA (Fig.4).

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



CONCLUSION

As of October 2023, Spain had reimbursed ~2 in 3 medicines centrally authorized by the EMA from 01/2018-12/2021, with a 22.5-month gap since the centralized authorization.

Corresponding authors: Mafalda Carmo, mafalda.carmo@iqvia.com

REFERENCES

1. EMA Website, Table of all European Public Assessment Reports. URL: https://www.ema.europa.eu/en/medicines/download-medicine-data.
2. EFPIA Patients W.A.I.T. Indicator 2022 Survey, April 2023.
3. Database developed by IQVIA Spain, aggregating data from different sources. 4. AEMPS Website. URL: https://cima.aemps.es/cima/publico/nomenclator.html. 5. CIPM Minutes Website: https://www.sanidad.gob.es/profesionales/farmacia/CIPMyPS.htm.
6. Bifimed Website: https://www.sanidad.gob.es/profesionales/medicamentos.do.

** The IQVIA Market Access Tracker also includes sales data (e.g., date of first sale in Spain and per Autonomous Community, date when sales reach a given target) as well as data on the received health technology assessments (informes de posicionamiento terapéutico). Data is available for new drugs and for new indications, although only the first are covered in the present analysis.*

ISPOR Congress, November 12-15 2023, Copenhagen, Denmark. Poster HPR204