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Health Technology Assessment of New Drugs in Spain: Understanding the Evaluators' Evidence Needs

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OBJECTIVES

- To describe the health technology assessment (HTA) of drugs authorized by the European Medicines Agency (EMA) in Spain and their potential relation to the drugs' reimbursement status.

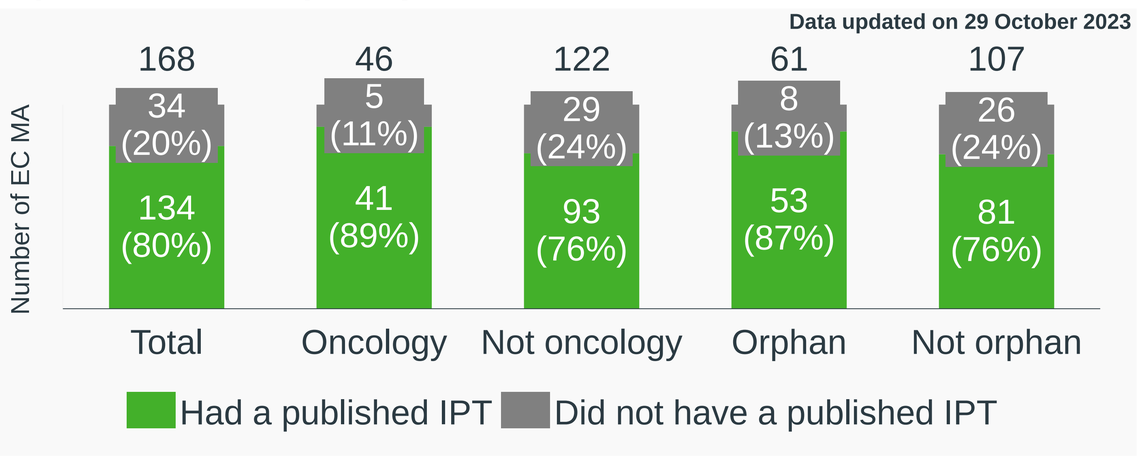
METHODS

- A list of human medicines centrally authorized from 01/2018-12/2021 was retrieved from the EMA website.
- The date of the Therapeutic Positioning Report ("IPT" from Spanish initials) publication was extracted from the Spanish Agency of Medicines and Medical Devices (AEMPS) website.
- IQVIA's HTA Accelerator database contains HTA publications from over forty countries and was used to extract detailed IPT data, when available, categorizing the evaluators remarks by type and as positive or negative.
- A product was considered reimbursed when included in the national reimbursement list as of 29th October 2023 (Nomenclátor).

RESULTS

- A total of 168 new medicines were authorized by the EMA during the study period, of which 134 (79.8%) had a published IPT in Spain by 29th October 2023 (Fig.1). The proportion of drugs with an IPT was higher in orphan (86.9%) and in oncologic drugs (89.1%).

Figure 1. Percentage of new medicines authorized by the EMA with a published IPT report by 29/10/2023



- One in five (17.2%) products without an IPT were reimbursed versus 82.8% of products with an IPT. A sample of 115 (85.8%) IPTs was available in IQVIA's HTA Accelerator as of 29/10/2023, of which 85.2% from reimbursed products (Fig.2).

Figure 2. Description of the analysed IPT sample vs total published IPT, per reimbursement status

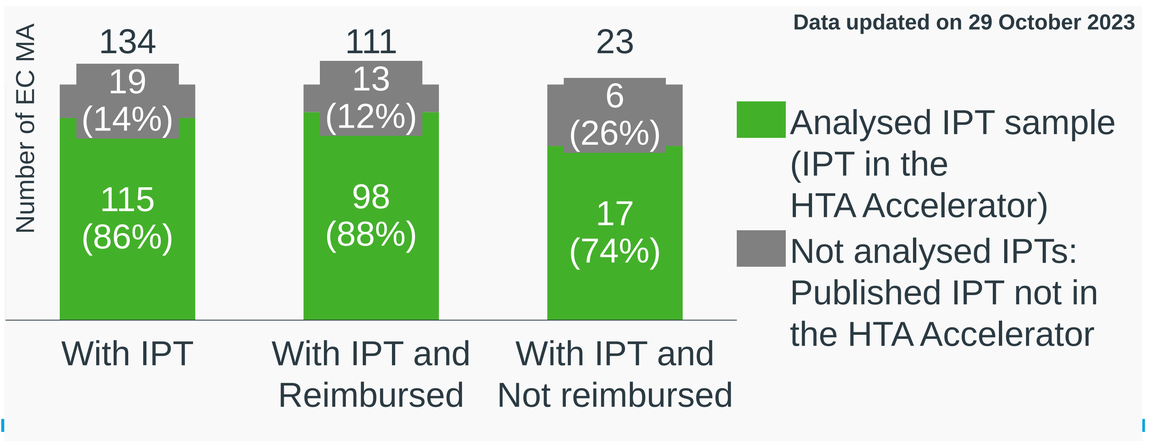
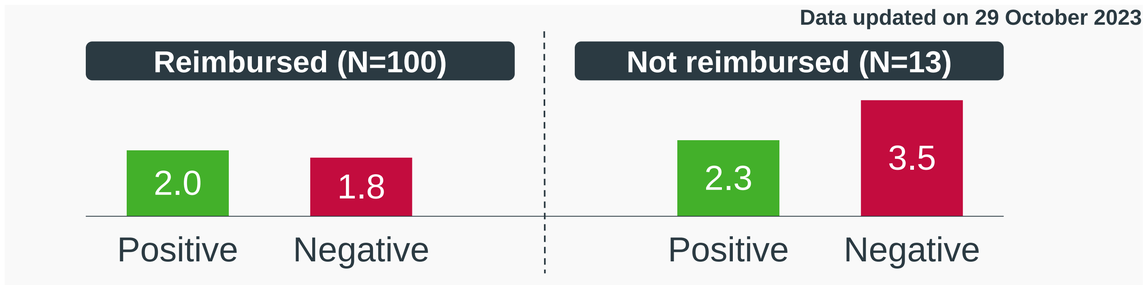


Figure 3. Mean number of clinical or economic positives and negatives stated in IPT conclusions per reimbursement status



- On average, 2 positive and 1.8 negative aspects were mentioned in the IPTs of reimbursed products versus 2.3 and 3.5, respectively, on IPTs of non-reimbursed products (Fig.3).
- Lack of direct comparator and increased risk of adverse events were the most stated negative aspects (Table 1), present in 26.1% of the analyzed IPTs.

Table 1. Negative clinical aspects stated in the IPT

	T	R	NR
Lack of direct comparator	30	25	5
Increased risk of adverse events	30	24	6
Lack of long-term safety data	26	23	2
Not providing relative data against appropriate comparator	22	19	2
Immature data	21	17	4
Small number of patients	18	16	2
Lack of long-term follow-up	15	13	1
Increased risk of severe adverse events	14	11	3
Lack of long-term efficacy data	14	12	1
Open-label trial design	14	9	5
Not providing efficacy data for the target subgroup	13	12	-
Limited additional benefit to existing treatment	10	6	4
No long-term data available	8	7	-
Lack of hard outcomes	7	6	1
Lack of long-term safety data	7	5	2
Heterogenicity within the study/among studies	6	5	1
No data on efficacy/safety for combination w/ other product	4	4	-
Inappropriate comparator in the clinical study	4	4	-
Study population different from target population in the submission	4	4	-
QoL data not evaluable	3	2	-
Indirect treatment comparison not well conducted	2	1	1
Treatment duration is too short	2	1	1
High risk of bias	2	1	1
Low ease of use	2	2	-
Not meeting primary endpoint	2	-	2
Unfavorable benefit – risk ratio	1	-	1
Not transposable/applicable to clinical practice	1	-	1

QoL, Quality of Life. NR, Not Reimbursed. R, Reimbursed. SoC, standard of care. T, Total.

- The most frequent positive factor was superiority versus non-SoC/placebo in the primary endpoint (Table 2), stated in 52.0% of the IPT of reimbursed products' vs 15.4% in non-reimbursed.

Table 2. Positive clinical aspects stated in the IPT

	T	R	NR
Superiority vs non-SoC (or placebo) in primary endpoint	56	52	2
Superiority versus SoC or best supportive care in primary endpoint	29	26	3
Good safety/tolerability	27	25	2
Superiority versus non-SoC (or placebo) in secondary endpoint	24	22	1
Similar safety profile to existing treatment	19	19	-
Non-inferior or similar efficacy as existing treatment	16	12	3
Unmet need	16	11	5
Favorable benefit - risk ratio	8	5	3
Manageable toxicity profile	7	4	3
Significantly improves QoL	6	6	-
Ease of use	5	5	-
Lower risk of adverse events	3	2	1
Superiority versus standard of care or best supportive care in secondary endpoint	2	2	-
Long-term data available	2	2	-
Innovative nature	2	2	-
Appropriate comparators included	1	1	-
No deterioration of QoL	1	1	-
Appropriate dosing regimen in trials	1	1	-
Appropriate study population	1	1	-

QoL, Quality of Life. NR, Not Reimbursed. R, Reimbursed. SoC, standard of care. T, Total.

CONCLUSION

Incorporating the evidence needs of evaluators in the study designs may help support reimbursement decisions.

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