Reimbursement Recommendations and Pricing Status of Non-Small Cell Lung Cancer Drugs Authorized in Spain

Cendoya Revuelta D[1], Minarro Jimenez C[1], Gauthier A[1]
[1]Amaris Consulting, Barcelona, Spain

#145525
HTA248

INTRODUCTION

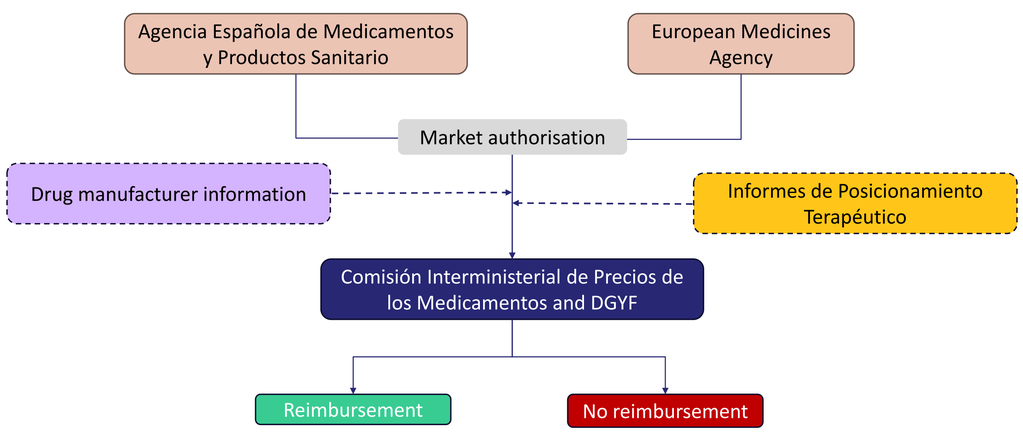
Lung cancer is the third most common form of cancer in Spain[1]

- Around **31,000 new cases of lung cancer** are diagnosed each year in Spain.[1]
- Lung cancer is the **leading cause of cancer-related mortality** in Spain, accounting for 20.3% of all cancer-related deaths in 2020.[2]
- **Non-small cell lung cancer** (NSCLC), accounts for 85**% of all lung cancer** cases.[3]

Advancements in the treatment of NSCLC have resulted in **new therapies** authorized by the European Medicines Agency (EMA)[4] and the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) in recent years.[5]

Patient access to reimbursed therapies follows a formalised process in Spain, involving several government organisations

Figure 1. Drug pricing and reimbursement process in Spain



Marketing authorisation and drug reimbursement in Spain. After a drug has received marketing authorisation, pricing and reimbursement decisions are made by the Comisión Interministerial de Precios de los Medicamentos (CIPM) and Dirección General de Cartera Común de Servicios del Sistema Nacional de Salud y Farmacia (DGCYF).[6]

- These decisions can be influenced by the **evaluation of information provided by drug manufacturers** and internal reimbursement recommendations formalized in **Informes de Posicionamiento Terapéutico (IPTs**).
- IPTs were introduced in 2013 to establish **clear and transparent criteria for the positioning of new medicines** to inform the CIPM's decisions; however, the role, perception, and legal binding of the IPTs in the pricing and reimbursement process has **encountered difficulties in its consolidation**.

OBJECTIVES

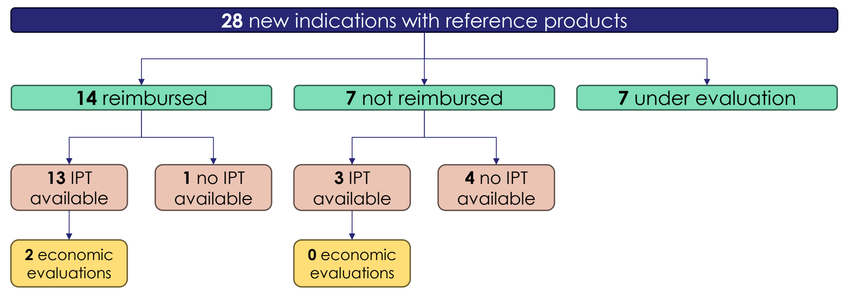
- This study aimed to evaluate the **reimbursement status of innovative NSCLC drugs approved in Spain**, and to examine the **impact of IPTs on reimbursement decisions for new drugs in this therapeutic area**.
- Additionally, the study seeks to identify **cases where IPTs and reimbursement decisions were not aligned**, and to analyse the **time between drug approval by the EMA and IPT publication**.

METHODS

- **NSCLC drugs authorized by the EMA since January 2019** were identified and information regarding the active substance name, approved indication, biosimilar/generic status, and marketing authorization date were extracted. For this analysis, only new reference products were of interest and biosimilar/generics were disregarded.
- The **associated IPTs**[7] were reviewed to extract and categorize information regarding reimbursement and positioning recommendation, criteria for decision-making, availability of economic evaluations, and publication date.
- Finally, the **CIPM reimbursement status** of these drugs was collected using BIFIMED[8] to understand if the IPT recommendation was aligned with the reimbursement status and under which conditions.

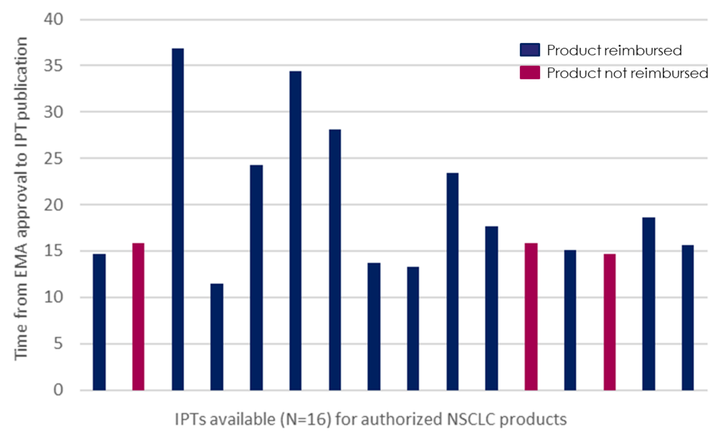
RESULTS

Figure 2. Reimbursement and evaluation (IPT) status of new indications approved in Spain



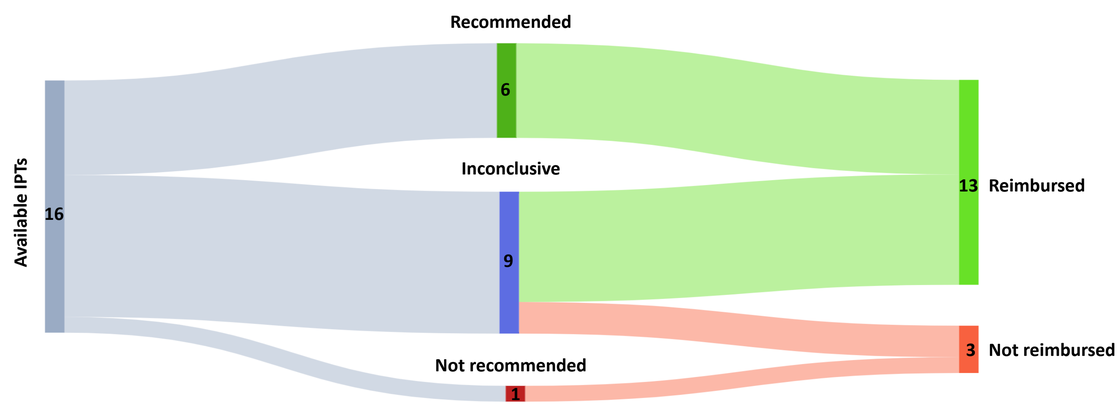
Approvals in NSCLC since 2019. Since 2019, the EMA has authorized 42 products in different NSCLC indications, including 14 biosimilars or generics. Among the 28 new reference products, 14 (50%) received government funding; of these, 13 (92.9%) were evaluated in IPTs, while 1 (7.1%) was not. Of the IPTs conducted for reimbursed products, only 2 (15.4%) included an economic evaluation. In total, 7 drugs (25%) did not receive funding, with 3 (42.9%) assessed in IPTs and 4 (57.1%) not evaluated. None of the IPTs available for non-reimbursement products included economic evaluations. Overall, of the 28 new reference products for NSCLC, 16 (57.1%) were evaluated in IPTs.

Figure 3. Time from EMA approval to IPT publication



Time from EMA approval to IPT publication, in months. The average time from EMA approval to IPT publication was 19.6 months, ranging from 11.5 to 36.8 months. There was no obvious correlation between reimbursement status and time between EMA approval and IPT publication. As the reimbursement date for new indications was not available in BIFIMED, the IPT publication date was considered as a surrogate.

Figure 4. Alignment between IPTs positioning and reimbursement recommendation and CIPM/DGYF decision



IPT positioning and reimbursement recommendation, and CIPM/DGYF decision. Of the 16 IPTs available, 6 (37.5%) provided a positive recommendation for the product, all of which led to reimbursement (100%). Conversely, 1 IPT (6.3%) issued a negative recommendation, which was also followed by non-reimbursement (100%). Finally, 9 IPTs (56.3%) were inconclusive in their recommendations; among these, 7 (77.8%) led to reimbursement, while 2 (22.2%) did not.

CONCLUSIONS

- Since 2019, both **new reference products and generics/biosimilars** have been approved by the EMA for the treatment of NSCLC. Among the new reference products, **50% are now reimbursed within the Spanish Healthcare System,** with an average delay of **19.6 months from EMA approval**.
- The findings of this investigation highlight the **distribution of reimbursement recommendations and the impact of positioning evaluations** on funding decisions for NSCLC drugs in Spain. Although there was **generally alignment between IPT recommendations and final reimbursement outcomes**, the absence of evaluations in some cases underscores the non-standardized role of IPTs within the broader drug approval process. Notably, economic evaluations were often excluded from IPTs, suggesting a **limited influence on pricing decisions thus far.**
- Regarding the timeline for IPT publication, the **average delay since EMA approval** may hinder timely access to NSCLC therapies.
- Finally, **inconsistencies in language and clarity within IPT conclusions** frequently made it **challenging to interpret the recommended positioning and reimbursement** status for the assessed products.

REFERENCES

1. SEOM. Las cifras del cáncer en España 2023. Available from: https://seom.org/images/Las_cifras_del_Cancer_en_Espana_2023.pdf
2. SEOM. Las cifras del cáncer en España en 2021. Available from: https://seom.org/images/Cifras_del_cancer_en_Espnaha_2021.pdf
3. GECP. Lung cancer incidence and Rick factors. Available from: https://www.gecp.org/incidence-and-risk-factors/?lang=en
4. European Medicines Agency (EMA). Available from: https://www.ema.europa.eu/en/medicines
5. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS). Available from: https://www.aemps.gob.es/
6. Gobierno de España. Documento informativo sobre la financiación y fijación de precio de los medicamentos en España. Available from: https://www.sanidad.gob.es/areas/farmacia/precios/docs/20220526_Doc_Infor_Financiacion_Med_Esp.pdf
7. AEMPS, Informes de posicionamiento terapéutico (IPT). Available from: https://www.aemps.gob.es/medicamentos-de-uso-humano/informes-de-posicionamiento-terapeutico/
8. BIFIMED- Buscador de la Información sobre la situación de financiación de los medicamentos. Available from: https://www.sanidad.gob.es/profesionales/medicamentos.do

DISCLOSURES

Authors have no conflict of interest to declare.

Presented at: ISPOR Europe 2024; 17-20 November 2024; Barcelona, Spain