ANALYSIS OF IPT DEVELOPED FOR THE NEW MEDICINES AND INDICATIONS AUTHORISED BY THE EUROPEAN COMMISSION DURING THE 2021-2023 PERIOD

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INTRODUCTION AND OBJECTIVE

- The Therapeutic Positioning Reports (IPT) were introduced at the end of 2012/13 to **create an evaluation system with a single assessment recognizable by the entire National Health System** (NHS) and offer a tool to support the price and reimbursement (P&R) process in the selective financing of medicines. [1] During the period 2013-2019 one study estimated that 214 IPTs were published and the mean time to draft report (Phase I) was 8,8 months and to publication 17,4 months. [2]
- In 2020, the **Action Plan for the Consolidation of the IPTs** was established through the creation of REvalMed, a drug evaluation network with different evaluation nodes. The plan changed the process of developing the IPT as well as the participating agents and the IPT format to include an economic evaluation, identification of patient subgroups and the information on therapeutic alternatives. One of its main objectives was to reduce elaboration times for the IPT. On June 2023, the **National Court annulled the Action Plan for the Consolidation of IPTs** of drugs in the NHS and since then no updated guidelines for the IPT process have been identified. [3,4]
- In previous work, it was felt that despite the potential limitations of REvalMed, it had **served as a step forward both in terms of the procedure itself** (with a clinical evaluation that assessed subpopulations and an economic evaluation that provided tools to assess drug inclusion) **and its multidisciplinary approach**. [5]
- The aim of this study is to **provide a description of the characteristics of the IPT developed by the Spanish Agency of Medicines and Health Products (AEMPS) for new medicines and indications (NMI) authorised by the European Commission (EC) over the course of the 2021-2023 period**.

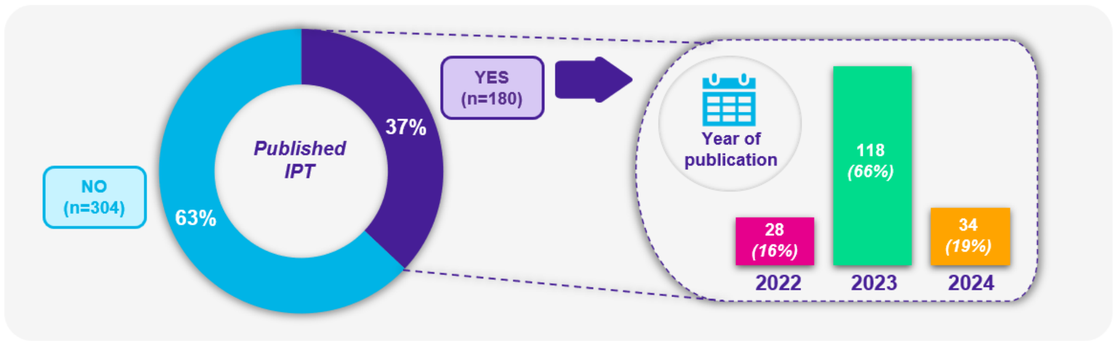
METHODS

- NMI authorised by the EC between 2021 and 2023 that included information regarding the Spanish IPT process were analysed.
- The data for the analysis were obtained from public online databases such as the AEMPS or the European Commission (EC) websites. [6,7]
- The main variables evaluated were:
  - the total number of IPT first draft and IPT published;
  - IPT initiation date, IPT first draft date and IPT publication date;
  - the therapeutic groups evaluated;
  - the positioning conclusions and the relationship between the reimbursement status and the positioning conclusions.
- A descriptive analysis of different variables of interest related to the IPT process was conducted.

RESULTS

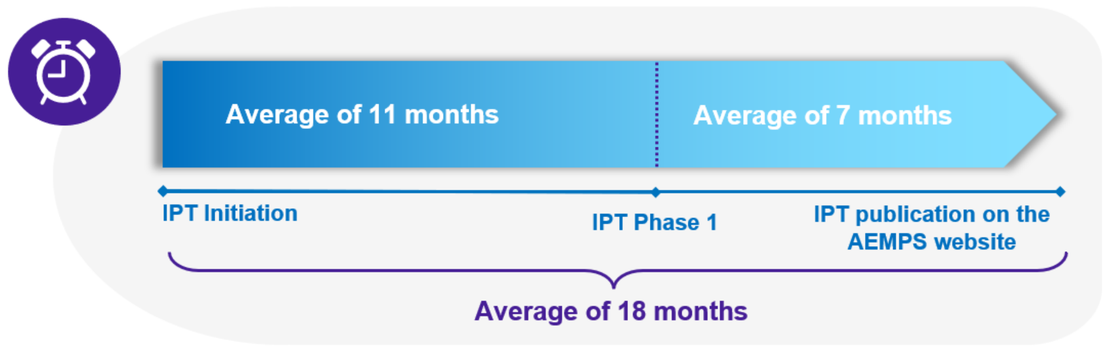
- During the period considered, of the 484 NMIs authorised by the EC, **180 NMIs (37%) had a published IPT,** while the remaining 304 NMIs (63%) did not have a published one. Most IPTs of the NMIs authorised between 2021 and 2023 were published on 2023 (Figure 1).

Figure 1. Number of IPT published and published per year



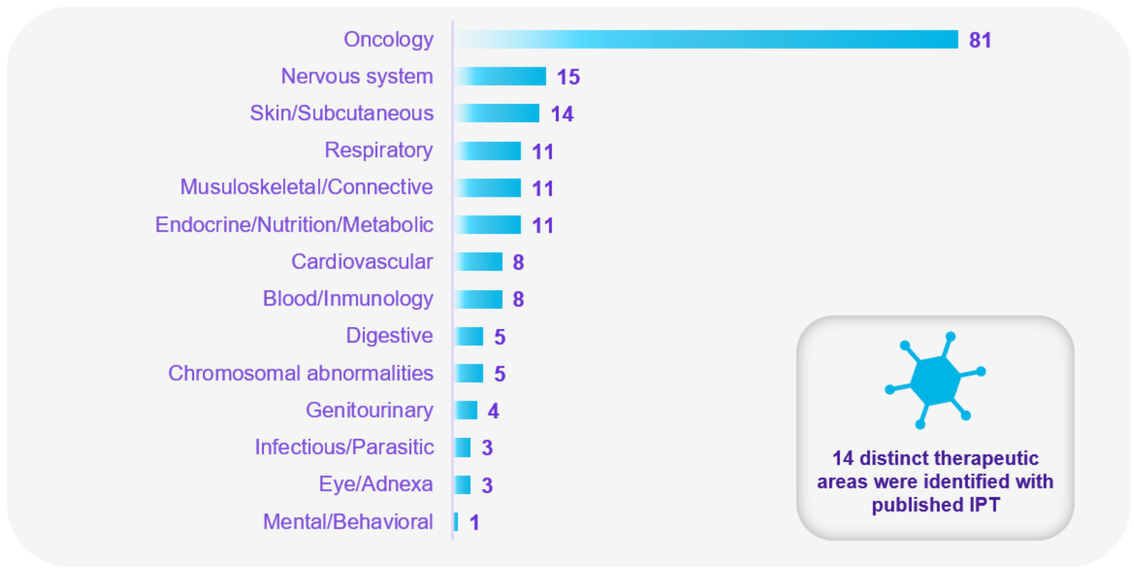
- The average time from IPT initiation to publication on the AEMPS website was 18 months. The average time from initiation to Phase 1 draft was 11 months (Figure 2).

Figure 2. Time from the start of the IPT to their publication on the AEMPS website



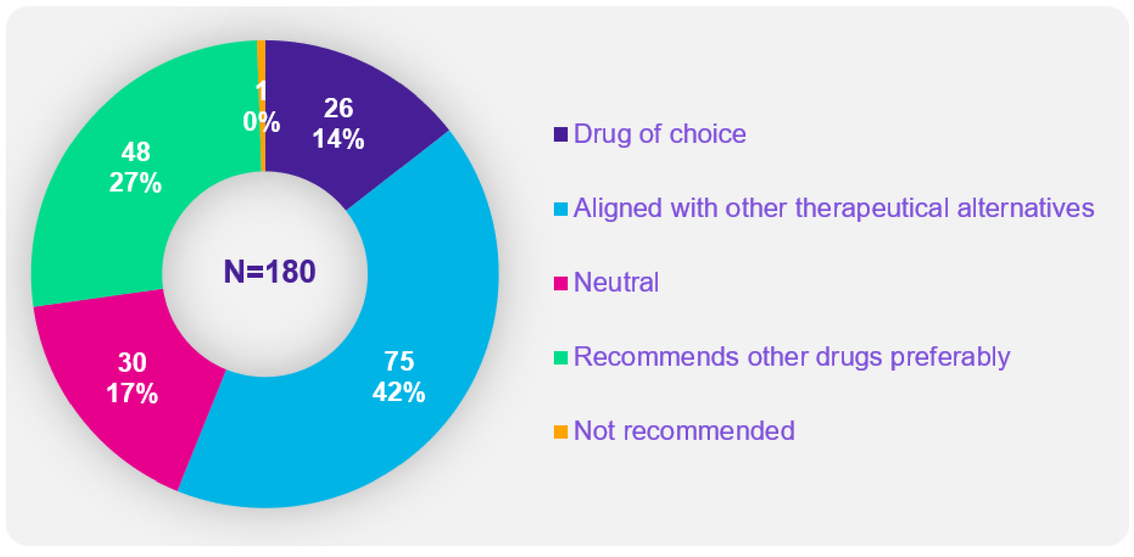
- The therapeutic area with the most published IPT was oncology (45%; n=81), followed by neurological diseases (8%; n=15) and skin or subcutaneous diseases (8%; n=14). The therapeutic areas with fewer published IPTs for NMIs were mental or behavioral diseases (0.5%; n=1), eye or adnexa diseases (1%; n=3), and infectious or parasitic diseases (1%; n=3) (Figure 3).

Figure 3. Number of published IPT by therapeutical area



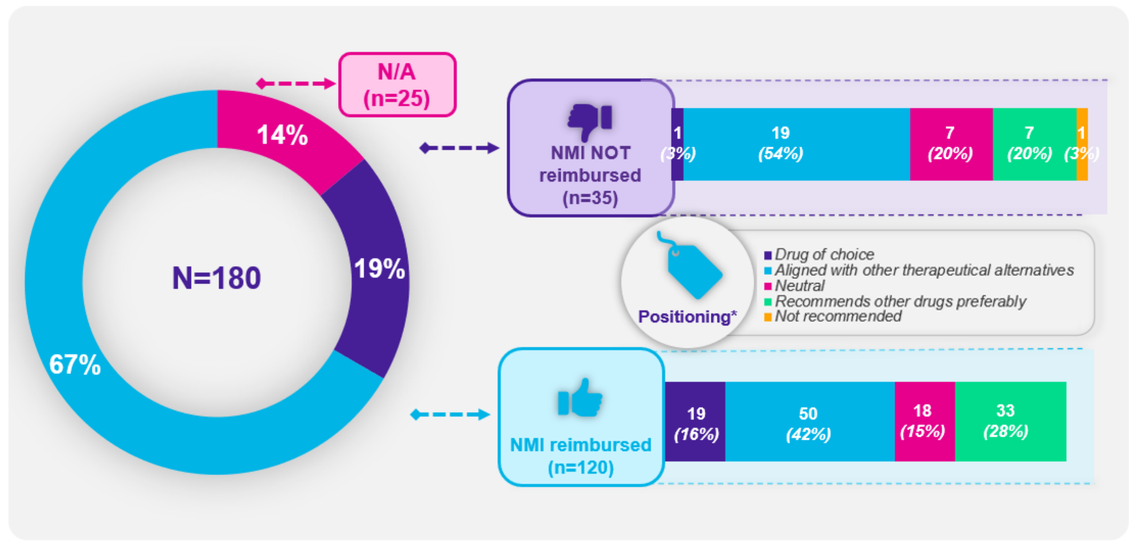
- Of all IPTs published during the period, 48 (27%) had conclusions that restricted the approved indication. On the other hand, 26 (14%) of NMIs were recommended as the drug of choice and 75 (42%) aligned with other alternatives (Figure 4).

Figure 4. Positioning based on IPT conclusions*



- Of all the 180 NMIs with published IPT, 120 (69%) were reimbursed whereas 35 (19%) were not reimbursed and there was no information on the reimbursement of the remaining 25 NMIs (14%) (Figure 5).

Figure 5. Positioning for both reimbursed and not reimbursed NMIs



- Within the **not reimbursed NMIs,** the positioning conclusions established restrictions in 23% (n=8) of the NMIs either recommending other drugs (n=7) or not recommending the NMI in question (n=1). Only one (3%) of the NMI evaluated was recommended as a drug of choice.
- Considering the **reimbursed NMIs,** 16% (n=19) were also recommended as the drug of choice whereas 28% (n=33) of them presented restrictions on the approved indication. None of the reimbursed NMI were positioned as not recommended.

CONCLUSIONS

The IPT were introduced to **provide a central tool for the positioning and economic evaluation of drugs in the Spanish National Health System and to optimize the evaluation process, reducing evaluation times.** According to the analysis carried out, **IPTs currently take between 1 and 2 years to be published and, therefore, to be made available to the public as a tool to support healthcare decision making. Nevertheless,** this analysis shows **the impact of the positioning conclusions on the reimbursement decision, illustrating their impact on decision making.**

NOTES AND REFERENCES:

*Self categorization based on the conclusions of the IPT. **Not recommended**: It is explicitly stated that the drug is not recommended; **Recommends other drugs preferably**: It is positioned in a further line than the authorised one, preferably positioning it in relation to other alternatives; **Neutral**: It is recommended according to its authorised indication without positioning it in relation to the alternatives; **Aligned with other therapeutical alternatives**: It is positioned in parallel to other therapeutic alternatives, in line with its authorised indication; **Drug of choice**: The drug is recommended in preference to the therapeutic alternatives.

(1) AEMPS; DGCF. Collaboration proposal for the development of therapeutic positioning reports for medications: Document approved by the Standing Committee on Pharmacy of the National Health System [Internet]. May 21, 2013. Available from: https://www.aemps.gob.es/medicamentosUsoHumano/informesPublicos/docs/propuesta-colaboracion-informes-posicionamiento-terapeutico.pdf (2) García V, et al. Aten Primaria. 2020;52(10):697-704. (3) Ministerio de Sanidad; AEMPS. Plan for the consolidation of therapeutic positioning reports (IPT) of medicines in the National Health System [Internet]. REvalMed SNS, 2020. Available from: https://www.sanidad.gob.es/areas/farmacia/infoMedicamentos/IPT/docs/20200708.Plan_de_accion_para_la_consolidacion_de_los_IPT.actCPF8Julio.pdf (4) Moliner F. Nullity of the IPTs Consolidation on Plan, risk or opportunity? Final judgment of the Spanish National High Court of 26 June 2023 declaring the nullity of the Consolidation Plan for TPRs [Internet]. 2023; 244. Available from: https://faus-moliner.com/wp-content/uploads/2023/11/2023-11-22-Nulidad-del-Plan-de-Consolidacion-de-los-IPT%C2%B4s-riesgo-u-opotunidad-ENG.pdf (5) Alegre del Rey et al. Rev. Ofil·ilaphar. 2023; 33 (4): 328-30. (6) AEMPS. Therapeutic Positioning Reports (IPT) [Internet]. 2024. Available from: https://www.aemps.gob.es/medicamentos-de-uso-humano/informes-de-posicionamiento-terapeutico/ (7) European Commission (EC) [Internet]. 2024. Available from: https://ec.europa.eu/health/documents/community-register/html/reg_hum_act.htm?sort=a