HTA292

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JCA is just about the corner…

is Spain ready for it?

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Background

The European Regulation on Health Technology Assessment (2021/2282) that defines the scope for Joint Clinical Assessments (JCA) will become mandatory for oncology drugs with new marketing authorizations starting in 2025, providing a combined European-level clinical assessment. For this purpose, the EUnetHTA21 network has developed methodological guidelines for conducting JCAs. In Spain, therapeutic positioning reports ("Informes de Posicionamiento Terapéutico", IPTs) assess the clinical value of drugs and guide decision-making on reimbursement and pricing at the central level. Given that IPTs and JCA focus on a clinical value assessment, JCA could potentially reduce time and resources needed for IPT development in Spain, provided the structure and decision-making drivers are aligned between the two. This study aimed to assess to what extent the drivers for decision-making proposed in the EUnetHTA21 methodological guidelines are currently employed in the development of IPTs in Spain, in order to better understand the potential impact of JCA on IPT development.

Methods

IPTs published in Spain between July 2023 and May 2024 were screened. To align with JCA's 2025 implementation staging, only IPTs for oncology drugs with new European marketing authorizations were included (n=16). The EUnetHTA21 methodological guidelines for JCA were reviewed and the drivers for decision-making were compared against those drivers for decision-making included in the IPTs. Each JCA driver for decision-making was classified as "**exhibiting similarity**", "**lesser stringency**" or "**greater stringency**" when compared to those in the IPTs.

Results

Ten domains within EUnetHTA21 guidelines for JCA were identified and compared against IPTs (**Figure 1**). For one domain, "Specifications for network meta-analyses" (Indirect comparison guidelines), it was not possible to conduct the comparison given that only two IPTs cited NMAs with different methodologies (random vs. fixed effects model).

- **4/10** drivers for decision-making of the IPTs were considered **similar** to the JCA.
  - The analyses presented on the IPTs were aligned with the requirements specified on the EUnetHTA21 guidelines. Therefore, a reduction in time and resources for IPT development can be expected due to the similarities in these domains.
- **4/10** drivers for decision-making of the IPTs were considered **less stringent** compared to the JCA.
  - The analyses presented in the IPTs were less rigorous than required by EUnetHTA21 guidelines. It can be expected that the transparency and robustness of IPTs could increase after JCA implementation, should AEMPS seek to incorporate JCA reports into its IPT process.
- **1/10** driver for decision-maker of the IPTs showed to be **more stringent** compared to the JCA, since IPTs include direct treatment comparisons.
  - It can be expected that IPTs are less likely to lead to positive outcomes if no H2H data is available

Figure 1: Comparison of selected drivers for decision-making in JCA vs. IPTs (n=16) in Spain.

JCA Guideline [1]	Requirement domains	IPTs [6]
Validity of clinical studies[2]	PICO mismatch	Any potential PICO mismatch are addressed in the IPTs
	Acceptability of trial types	All 16 IPTs analyzed comply with JCA guidelines
	Utilization of RWE	RWE can be leveraged when needed in IPTs
	RoB assessment	Half of the IPTs analyzed did not include mention to RoB
Outcomes (endpoints)[3]	Required safety reporting	Safety outcomes are reported systematically in all IPTs
	HRQoL inclusion	IPTs can include HRQOL outcomes
Applicability of evidence[4]	Subgroup requirements	10/16 IPTs analyzed do not comply with JCA guidelines
	Sensitivity analysis	All 16 IPTs analyzed do not comply with JCA guidelines
Indirect comparisons[5]	Type of ITC which is accepted	IPTs analyses are based on direct evidence from RCTs
	NMA specifications	Only 2 IPTs cited an NMA with different methodologies

Abbreviations: HRQoL: Health-related quality of life; IPT: Positioning Therapeutic Reports; JCA: Joint clinical assessment; PICO: Population, Intervention, Comparator, Outcome; RoB: Risk of bias; RTC: randomized controlled trial: RWE: real-world evidence

Comparison between ITP and JCA drivers for decision-making

Similar | IPT less stringent | IPT more stringent | Not evaluable

Conclusions

The drivers for decision-making for the clinical assessments of drugs when developing IPTs are overall aligned with those expected for JCAs. Consequently, JCA will likely provide a valuable framework for IPT development with little expectations for additional data requirements by the AEMPS, potentially reducing time for IPTs development and time to initiate price and access negotiations in Spain. JCA will also represent an opportunity for the AEMPS to improve the robustness and transparency of IPT content, given that 4/10 domains were considered less stringent than the JCA requirements. Manufacturers should consider shorter timelines for IPT development in Spain when deciding on launching sequence for European markets.

REFERENCES

[1] European Parliament 2021. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU.

[2] EUnetHTA 21. Individual Practical Guideline Document. D4.6: Validity of clinical studies.

[3] EUnetHTA 21 2022. Individual Practical Guideline Document. D4.4: Outcomes (endpoints).

[4] EUnetHTA 21 2022. Individual Practical Guideline Document. D4.5: Applicability of evidence-Practical guideline on multiplicity, subgroup, sensitivity and post hoc analyses.

[5] EUnetHTA 21 2022. Individual Practical Guideline Document. D4.3.1: Direct and indirect comparisons.

[6 AEMPS. Informes de Posicionamiento Terapeutico (2023). Available at: https://www.aemps.gob.es/medicamentos-de-uso-humano/informes-de-posicionamiento-terapeutico/?lang=en

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