Getting Ahead of the JCA: A Tiered Country Prioritization Framework for Predictive PICO Scoping

HPR164

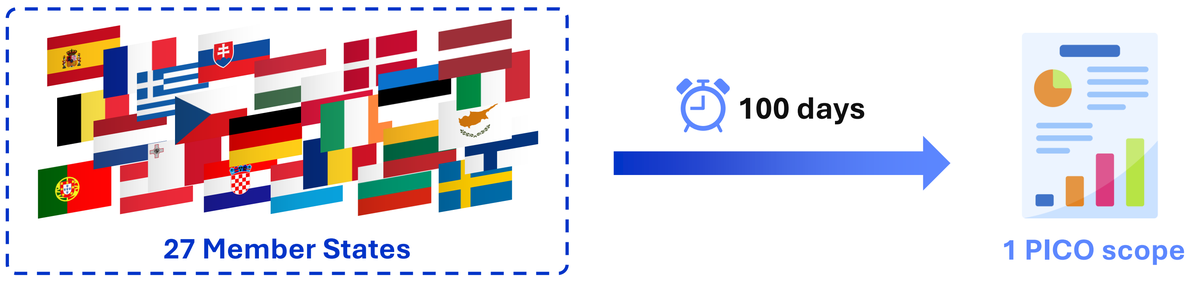
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Background and Objective

The JCA centralises the assessment, not the expectations

- Since January 2025, new oncology medicines and ATMPs receive one Joint Clinical Assessment (JCA) for all 27 EU member states (MS), in a single submission.
- National differences don't disappear. They surface in the PICO scope, where each MS adds its own populations, comparators and outcomes.
- Comparators drive the spread: MS define them by current practice, reimbursement status, likely displacement or cost-effectiveness.
- Each comparator sets the indirect comparisons needed. With 100 days from scope to dossier, late-found gaps have European-scale consequences.



Objective

Identify the minimum set of MS whose public evidence captures the PICO variation likely to appear in the JCA scope.

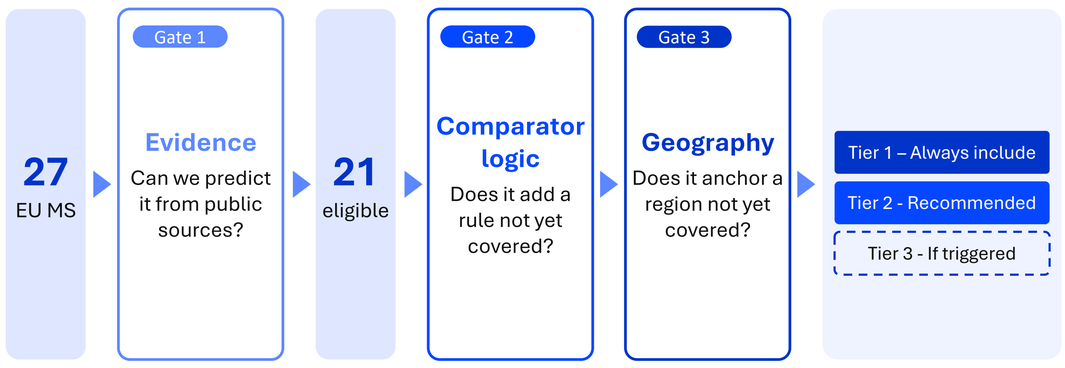
Methods

From 27 countries to the few that add something new

- TLR of public evidence to map all 27 MS: HTA reports and methods guidelines as primary sources; clinical guidelines, literature and reimbursement lists to validate.

- Each MS was assessed on three domains, applied in order: **evidence availability, comparator logic, geographic coverage**. An MS was only prioritised if it added something not yet covered.

- MS not eligible or adding nothing new are **represented by a regional proxy**.



Results

Comparator definition	Tier 1 – Always include	Tier 2 - Recommended
Current clinical practice	FR, IT, ES	PL, DK
Best standard treatment	DE	-
Most cost-effective treatment	NL	-
Most likely replaced treatment	-	BE
Reimbursed standard of care	-	BG

Tier 3 – If triggered

4 clusters · 7 MS

No new definitions

Adds within-definition variation and regional depth, only when the indication or business needs calls for it:

Nordic (FI, SE)
If Nordic emphasis or hospital-only pathway

Central-West (AT, IE)
If Central Western European emphasis

South (PT)
If Southern European emphasis

East (SK, EE)
If Eastern European emphasis

9 member states
Tier 1 + Tier 2: the recommended default predictive scope

Nine countries capture the variation

- The evidence landscape is wide but uneven: about half of MS publish structured HTA outputs; others offer only clinical guidelines or thin, fragmented evidence.

- Five national comparator definitions were found, with variation within them: Denmark requires all commonly used options, Finland a same-class comparator for hospital and ATMP products.

Discussion

Targeted beats exhaustive

- **Selecting countries by the variation they add, not by market size, gives every inclusion a stated reason.** That makes the scope defensible internally and to affiliates.
- The framework is a starting point, not a rulebook. **Countries can be swapped per indication, as long as coverage holds.**
- **Public evidence has a ceiling:** it predicts national positions, not how the assessment scope is consolidated. Structured stakeholder engagement closes that gap.
- Limitations: the tiers capture comparator and geographic variation, not subpopulation or outcome requests. **Prospective validation in live JCAs is needed.**

Removing a country? Ask two questions:

1. **Is its comparator logic still represented?**
2. **Is its region still represented?**
   If not, a source of PICO variation is lost.

Conclusion

Predict the scope before the clock starts

- The JCA scope can be anticipated without screening all 27 MS.
- Nine MS, chosen for comparator logic and geography, form a credible default predictive scope.
- Starting before scope release moves developers from reactive dossier preparation to anticipatory evidence planning.

General information

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