How Can the Marketing Authorization Holders be Ready for the Implementation of the Joint Clinical Assessments in 2025?

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OBJECTIVES

In January 2025, the European Commission will implement new health technology assessment (HTA) regulations, namely joint clinical assessments (JCA) for oncology medicines and advanced therapy medicinal products[1]. Pricing and reimbursement decisions will remain under the purview of European Union (EU) HTA bodies, which will determine the added value for their health systems[1]. Uncertainties persist for Marketing Authorization (MA) holders, demanding for refined management of the HTA process. This study aimed to understand how available evidence influences the HTA process up to reimbursement decisions.

METHODS

The study involved a comprehensive investigation into the EMA and INFARMED domains to gather relevant regulatory and evaluation criteria. A task force of experienced pharmacists and health economists was established to discuss strategies for optimizing the preparation and prediction of the HTA process and to evaluate how existing evidence influences HTA.

RESULTS

The PICO framework (Population, Intervention, Comparators, Outcomes) produced by the JCA will be the foundation of the HTA process. For MA holders, predicting the PICO in advance and understanding the epidemiology of the disease will be essential for a successful HTA strategy, offering early insights and assessing alignment with each EU country settings. Align with this feasibility analysis, evidence gaps should also be identified, determining if there is enough evidence or if new evidence must be generated via methods like Network Meta-Analysis or Indirect Treatment Comparison. Understanding these gaps and their impact on decisions ensures MA holders effectively navigate the HTA process, aligning strategies with European healthcare systems' requirements.

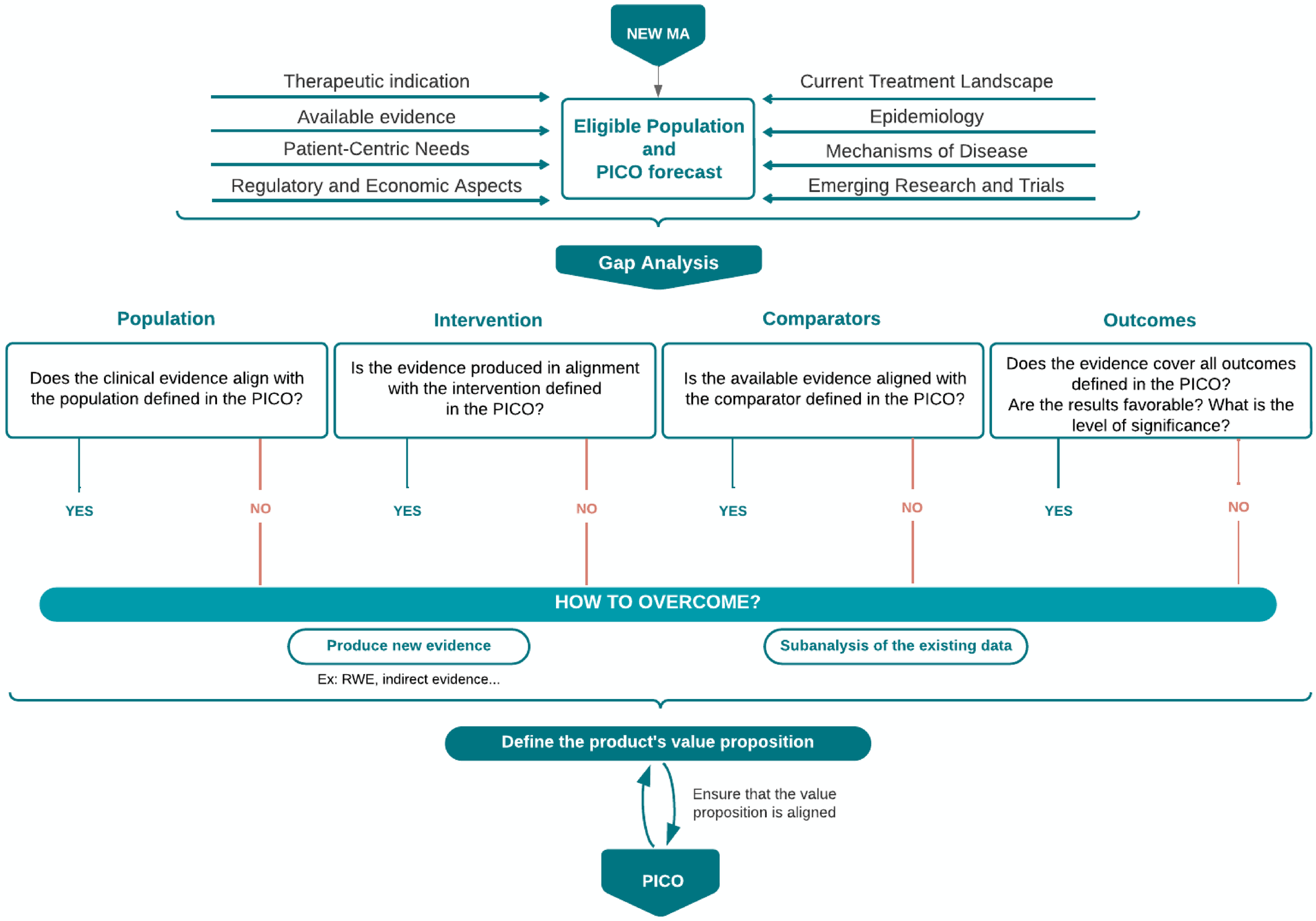

Figure 1. Feasibility and Gap Analysis Framework for HTA Risk Management.
MA: Marketing Authorisation; RWE: Real World Evidence.

CONCLUSIONS

Conducting a feasibility and gap analysis of existing evidence prior to obtaining the PICO framework will be crucial for MA holders and will enhance the predictability and risk management of the HTA process. A strategic and well-designed evidence plan can provide companies with an opportunity to mitigate PICO issues, limit uncertainty, and strengthen a JCA dossier.

[1]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