Lost in PICO? A simulation of the EU HTA scoping process



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OBJECTIVES

The joint clinical assessment (JCA) according to Regulation (EU) 2021/2282 will initially be implemented for oncology drugs and ATMPs from January 2025. All JCA procedures are commenced by the scoping process: The formulation of a member state-specific research question, represented as individual PICO schemes. Patient population, intervention, comparator, and study endpoints to measure the outcome are determined by the authorities as basis for clinical evaluation. Given the diversity of standards of care in Europe, multiple PICOs can be demanded. By simulating an EU HTA-like scoping process as of today, this analysis aims to assess the risk of receiving numerous PICOs.

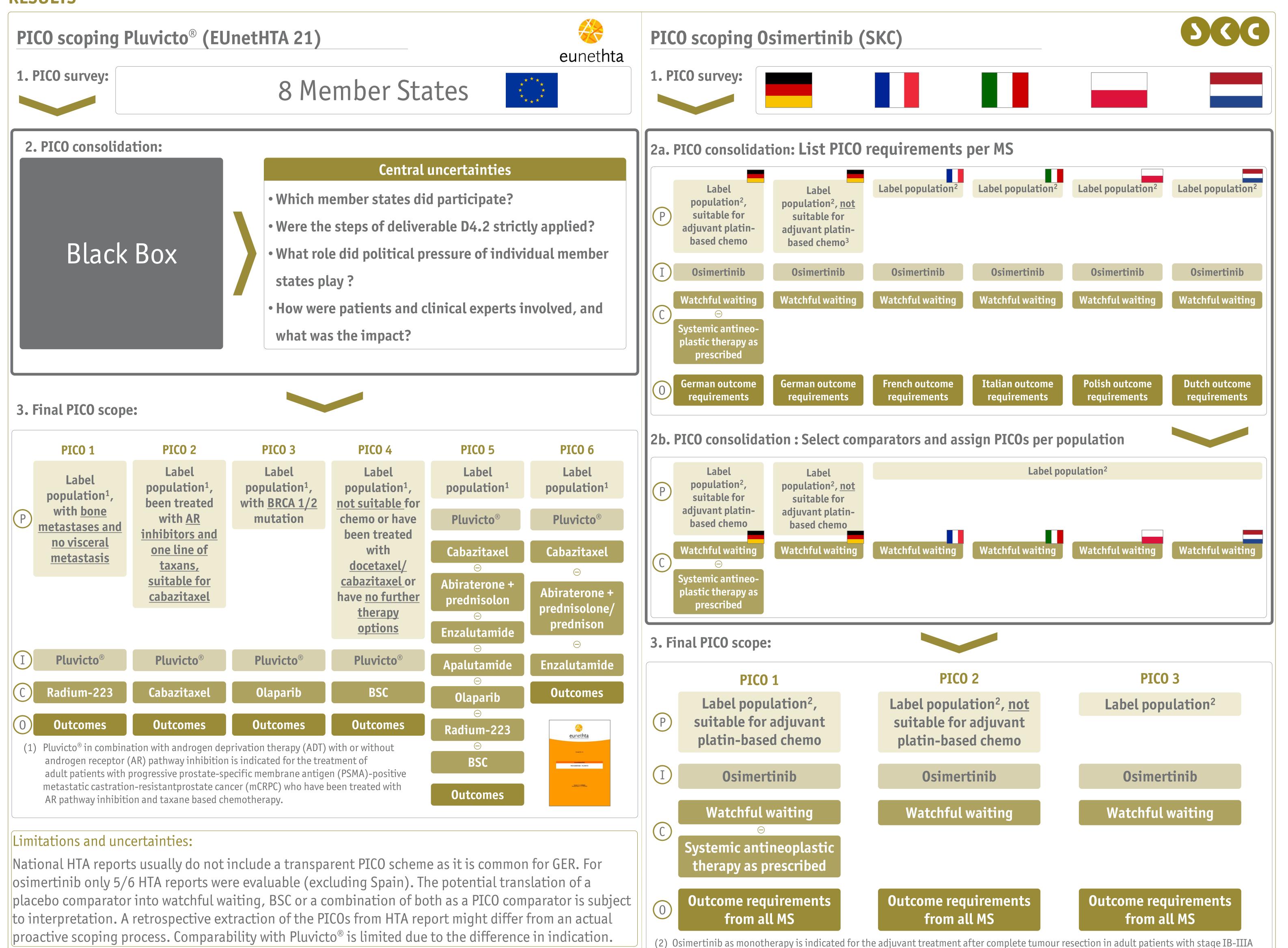
Abb.: AR: Androgen receptor; BSC: Best Supportive Care; Chemo: chemotherapy; EU: European Union; HTA: Health Technology Assessment; HTD:

Health Technology Developer; JCA: Joint Clinical Assessment PICO: Patient, Intervention Comparator, Outcome; ⊝:OR conjunction.

METHODS

To determine the potential heterogeneity of PICO schemes, completed national HTA assessments from the "EU big 6" member states were compared regarding several oncology drugs. The PICO schemes for osimertinib (subsequently presented), venetoclax and pembrolizumab were extracted from the available national HTA reports and subsequently consolidated using the process described in the EUnetHTA 21 deliverable D4.2. In addition, the results of this analysis were then compared to the results of the EUnetHTA 21 PICO exercise for Pluvicto® to understand the factors influencing the HTA authorities in a PICO scoping process under realistic conditions.

RESULTS



Conclusion & Discussion

Extracting PICO schemes from available HTA reports from Germany, France, Italy, Poland, Netherlands and Poland and applying the PICO consolidation steps from EUnetHTA 21 deliverable D4.2 resulted in 3 PICOs (from 5 countries) for osimertinib, 1 PICO for (from 6 countries) venetoclax and 2 PICOs (from 6 countries) for pembrolizumab. Comparing these results with the EUnetHTA 21 PICO exercise for the oncologic product Pluvicto[®], the following conclusions can be drawn:

- Strictly applying the consolidation rules appears to lead to potentially fewer PICOs than the Pluvicto® exercise, suggesting that the process is likely more political than it is logical.
- Therefore, anticipating and preparing PICOs, especially considering the demands of influential countries like Germany will be crucial for a favorable JCA outcome of a specific product.
- In addition, evaluating the strategic implications of receiving disadvantageous comparators (price anchors) and populations (subpopulations for which no evidence may be available) in the JCA which might then be brought also into national HTA procedures will be essential.

The presented analysis emphasizes the importance for HTDs of initializing strategic, structural and operative preparations for the upcoming EU HTA process, both in general and product specific.



EU HTA is just around the corner and pharmaceutical companies will only have 90 days to produce the final JCA dossier. To perfectly orchestrate all workstreams into this tight timeline, one needs robust, convincing evidence and a comprehensive strategy that can anticipate and prioritize likely scenarios. Only through such an approach can one achieve the desired national price. That is why Numerus and SKC have combined their expertise in the collaborative solution - JCA90. With JCA90, we support our clients in mastering EU HTA. Visit our joint stand C2-043 at ISPOR Copenhagen.

substitution mutations.



All analyses have been generated by data from SKC's proprietary MAIS (Market Access Intelligence System = MAIS) database. This database contains and links information on completed and ongoing benefit assessments according to §35a SGB V of the German Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA). The MAIS-database records and evaluates relevant information from the dossier, the benefit assessment by IQWiG or the G-BA, the G-BA resolution as well as the Lauer-Taxe. It also contains an up-to-date overview of all procedures and their status.





nonsmall cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R)