Alignment of EU HTA and member state clinical assessments and the potential impact on value perception

HTA189

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INTRODUCTION

- From 2025, oncology treatments will be the first therapy area to be mandated to be assessed using the Joint European Union Health Technology Assessment (EU HTA) process for clinical evaluation
- The Joint EU HTA aims to expedite patient access by reducing duplication of efforts across HTAs in the region[1]
- However, current submissions across the member states (MS) are variable, with different types and levels of information requested

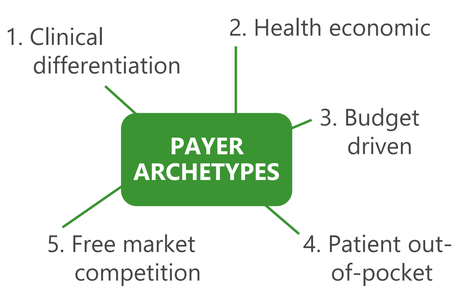
OBJECTIVES

- The research aim is to understand if the EU HTA Joint Clinical Assessment (JCA) supports the objective of expediting patient access by reducing duplication
- The objective is to determine the level of overlap between MS assessments and the Joint EU HTA to understand how the content of the EU Joint HTA will add value

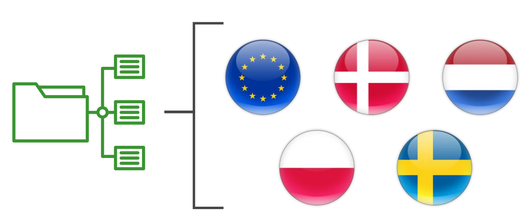
METHODS

Figure 1. Methods flow diagram

4 of the EU27 markets were chosen to cover a range of archetypes (Table 1)



Clinical dossier templates, HTA assessments and other publicly available materials were identified in those markets and for the EU Joint HTA



Country HTA documents were compared to the JCA dossier template to assess the alignment:

- Overlapping sections were calculated using the following: 1-number of sections in the JCA dossier & MS dossier/ number of sections in the JCA dossier
- Additional qualitative assessment was conducted for the content of the sections

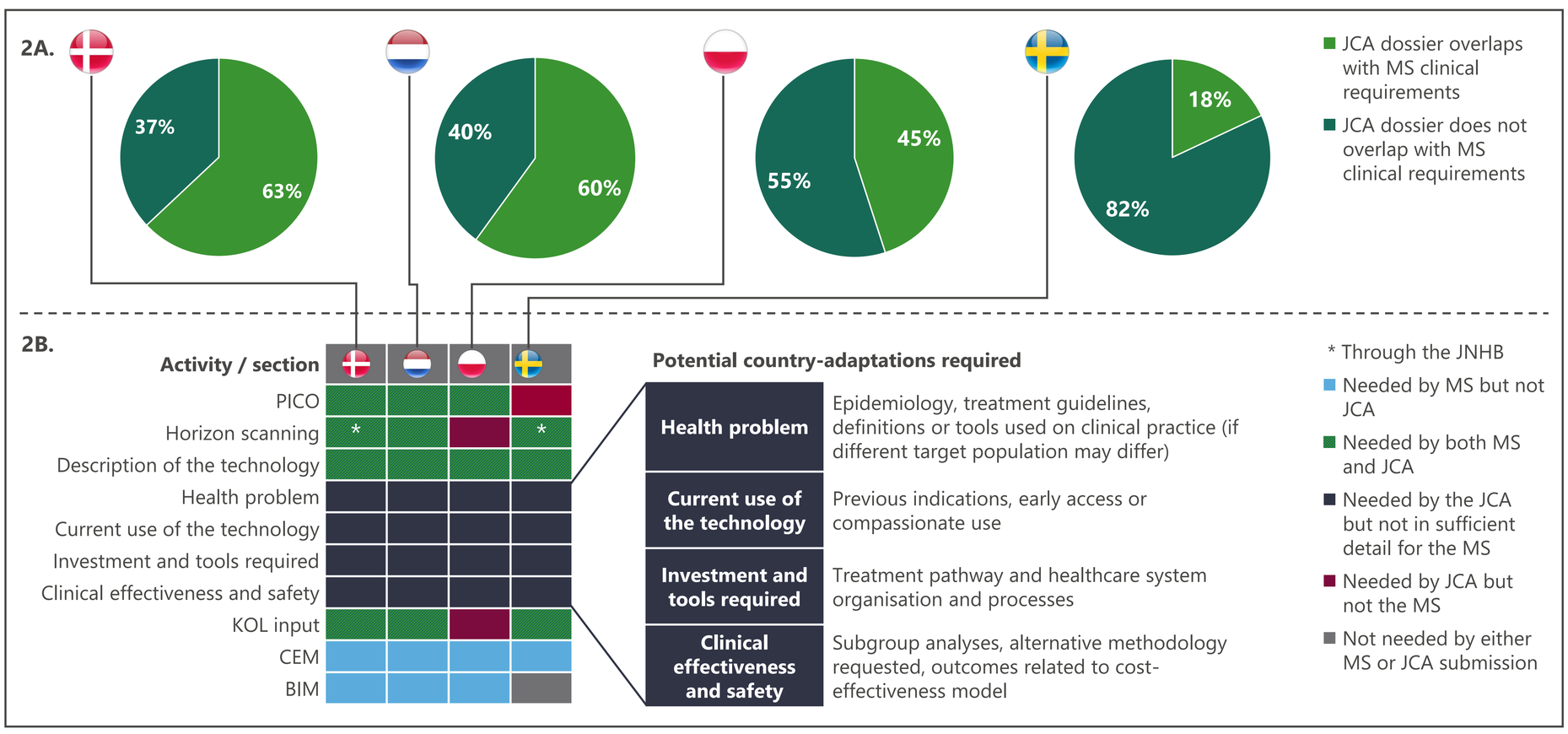
Table 1. Payer archetyping

Archetype	Primary goal	Countries
Clinical differentiation	Compares the clinical evidence for similar products to assess the most valued	
Health economic	Rational methodology for comparing value for improved outcomes	
Budget driven	Efficiently allocating the limited budget / resources	

RESULTS

- While the JCA dossier covered all the clinical effectiveness and health burden sections required for MS HTA submissions, it also contained additional content that was unnecessary (Fig. 2A)
- The additional information in the JCA dossier were typically current technology use and comparator clinical effectiveness
- MS HTA submissions require country-specific data, typically missing from the JCA dossier, reducing its usability for local HTA submissions (Fig. 2B)
- A comparison between a recent EUnetHTA submission and subsequent MS HTA submissions showed that the latter required additional adaption and data to strengthen the local value story and ensure cohesion between the clinical and economic submissions
- Therefore, JCA submissions are unlikely to be fully suitable for local HTA purposes without significant adaptation

Figure 2A. Percentage of overlap between the sections of the MS clinical requirements and the JCA dossier
Figure 2B. Heatmap of the overlap and alignment between member state and JCA submissions



CONCLUSIONS

THE NEED FOR COUNTRY-SPECIFIC VALUE PRESENTATION MAY REDUCE THE INTENDED EFFICIENCY GAINS OF THE EU HTA

1. Whilst the JCA will enable a summary of clinical data and health burden information to be used in the MS HTA submission, this analysis shows that manufacturers would have to submit additional clinical and economic data to satisfy local requirements
2. This may reduce the efficiency with which MS HTA bodies are able to determine added value from the JCA report
3. It is unclear from this analysis if the JCA will achieve its objectives of expediting patient access by reducing duplication
4. Therefore, initial resource savings from JCA may be redundant due to the supplemental activities required by both parties to support value perception and health economic evaluation adequately

REFERENCES

1. On health technology assessment and amending Directive 2011/24/EU. Eur-Lex. Accessed 7th Oct 2024 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32021R2282

Abbreviations: *BIM: Budget impact model; CEM: Cost-effectiveness model; THA: Health technology assessment; JCA: Joint clinical assessment; JNHB: Joint Nordic HTA Body; KOL: Key opinion lead; MS: Member state*

ISPOR Europe | 17 – 20 November 2024 | Barcelona, Spain